UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IRON WORKERS DISTRICT COUNCIL OF NEW ENGLAND HEALTH AND WELFARE FUND, UTAH-IDAHO TEAMSTERS SECURITY FUND, JACKSONVILLE POLICE OFFICERS AND FIRE FIGHTERS HEALTH INSURANCE TRUST, and NYST COUNCIL HEALTH & HOSPITAL FUND, on behalf of themselves and others similarly situated,

Plaintiffs,

v.

TEVA PHARMACEUTICAL INDUSTRIES LTD.; TEVA PHARMACEUTICALS USA, INC.; TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.; and NORTON (WATERFORD) LTD.,

Defendants.

Civ. No. 23-cv-11131 (NMG)
JURY TRIAL DEMANDED

AMENDED CLASS ACTION COMPLAINT
AND DEMAND FOR JURY TRIAL

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I. INTRODUCTION

1. The federal drug laws strike a careful balance between rewarding drugmakers for innovation and ensuring public access to medication at reasonable prices. To incentivize innovation, brand-name drugmakers receive a period of patent exclusivity during which they can—and do—charge astronomical prices for life-saving medications. Immediately after that exclusivity period ends, however, the drug laws allow affordable generic products to enter the market.

2. While generic products save billions of dollars a year for patients, health plans, and other entities that pay for prescription medication, they are a threat to brand-name drugmakers' thirst for profits. Once a generic drug enters the market, it quickly erodes brand-name sales and, in turn, profits. As a result, some brand-name drugmakers seek to unlawfully prolong their period of patent exclusivity through a variety of anticompetitive and deceptive tactics.

3. The defendants in this action, Teva Branded Pharmaceuticals R&D, Inc. and its affiliates, embarked on a nearly decade-long (and continuing) anticompetitive scheme to delay generic competition for QVAR, its blockbuster line of brand name asthma inhalers.

4. QVAR is a drug-device combination: an asthma medication called beclomethasone dipropionate HFA placed into an inhaler device. In the mid-to late-2000s, Teva acquired the rights to QVAR, a medication that millions of people rely on to prevent life-threatening asthma attacks.

5. QVAR's lawful period of patent exclusivity was set to expire in July 2015. But that was too soon for Teva. So Teva perpetrated a full panoply of

anticompetitive delay tactics that both collectively and individually violate the antitrust laws to extend its exclusivity and continue charging astronomical prices.

6. *First*, as patent expiry neared, Teva submitted two device patents for listing in the U.S. Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") that did not belong there because they did not claim QVAR's drug product (beclomethasone dipropionate HFA). These improper listings allowed Teva to file patent litigation against would-be generic competitors to automatically block their market entry for 30 months.

7. *Second*, Teva executed a "product hop"—i.e., making an unrequired change to a mechanical aspect of the inhaler that delivered the brand drug product to impede generic substitution at the pharmacy counter. Teva obtained FDA approval to change QVAR's inhaler device so that it could place QVAR's drug product (beclomethasone dipropionate HFA) into a new device called the QVAR Redihaler and stop selling the original QVAR product. In doing so, Teva stifled would-be generic competitors to QVAR because the drug laws do not allow for generic substitution of a given drug-device combination unless the generic is approved for that specific drug-device combination. As a result, QVAR generic equivalents could not be substituted for QVAR Redihaler. Nor could they be substituted for QVAR because Teva pulled it from the market.

8. *Third*, Teva stuffed the Orange Book with twelve patents that Teva told the FDA, under penalty of perjury, claimed the QVAR Redihaler drug product

(beclomethasone dipropionate HFA) when most did not. In fact, Teva did not obtain and submit a patent that (if valid and if applicable) could qualify as an Orange Book listing for the QVAR Redihaler until almost three years after the FDA approved the product. But by improperly submitting for listing other non-qualifying device patents, Teva ensured it could preemptively file patent litigation to automatically block would-be generic competitors from entering the market during that initial three-year period of time.

9. *Fourth*, despite having pulled the original QVAR from the market by implementing the hard product hop to QVAR Redihaler described above, Teva subsequently submitted seven patents for listing in the Orange Book that the company wrongfully represented claimed the original QVAR drug product. Yet none of the patents that Teva submitted for listing in the Orange Book for the now discontinued QVAR drug product claimed beclomethasone dipropionate in combination with an inhaler device and were, therefore, improperly listed. Teva listed these patents to force three would-be competitors to risk patent litigation that would preemptively block them from entering the market with the original QVAR product.

10. *Fifth*, Teva engaged in objectively meritless "sham" patent litigation against two of the three would-be competitors to delay generic competition. Indeed, but for Teva's unlawfully listed patents, it would not have had standing to file patent litigation before a competitive product launch in the first instance.

11. What's more, Teva dismissed most of its meritless infringement claims against the second and third competitors over the course of the patent litigation, on

a piecemeal basis, to drag the litigation out while ensuring that the validity and/or infringement of its patents could not be adjudicated, and that key patents would remain a roadblock to competition, regardless of the outcome of the litigation. To be sure, Teva's litigation goal was not to protect its patents in good faith, but instead to buy a two-and-a-half-year (and more) delay in competition.

12. *Sixth*, instead of suing the first would-be competitor, on information and belief, Teva entered into a reverse payment agreement—i.e., an agreement where the generic competitor refrains from launching its product—to bottleneck all competition. Under FDA law, the first generic applicant is eligible for six months of marketing exclusivity during which time all other generic applicants must wait before launching their products. By reaching an agreement with the first applicant not to launch, Teva could block *all* competition, including the second and third applicants that it sued.

13. Normally, agreements like the one between Teva and its first would-be competitor play out in the context of litigation. But Teva knew from its own past experience as a generic company that if it reached an agreement *without* suing, it could bottleneck the competition indefinitely.

14. That is exactly what it did: although Teva's last valid drug-product patent expired in July 2015, there is *still—today*, eight years later—no generic version of QVAR available to patients, and health plans and other payors are continuing to pay supracompetitive prices to ensure that their members can breathe.

15. Even eight years of improper monopoly is not enough to slake Teva's greed. Teva recently announced the next phase of its anticompetitive scheme: it plans

to—sometime in the near future—execute a second product hop, from the QVAR Redihaler to yet another inhaler device called the QVAR Digihaler. If Teva's anticompetitive scheme is not brought to a halt, that product hop could extend Teva's unlawfully prolonged monopoly for another *twenty years*.

16. Were it not for Teva's overarching anticompetitive scheme, affordable generic versions of QVAR would have become available years ago. Indeed, generic QVAR has been marketed and sold for years outside the United States, including in the UK, India, and Australia. Pharmacists would have substituted affordable generic QVAR for more expensive brand-name prescriptions. And the plaintiff and members of the class would have saved, collectively, hundreds of millions, if not billions, of dollars in prescription reimbursements.

17. This suit is brought under federal and state antitrust laws and state unfair trade practices law to recover the overcharges sustained by end-payors for QVAR and QVAR Redihaler, and to enjoin further extensions to Teva's unlawful monopoly.

II. PARTIES

18. Plaintiff Iron Workers District Council of New England Health and Welfare Fund is a multi-employer health and welfare plan headquartered in Massachusetts that provides self-funded healthcare coverage to thousands of employees and their family members. During the class period, as defined below, Iron Workers purchased, paid, and/or provided reimbursement for some or all of the purchase price of QVAR and QVAR Redihaler for the personal and/or household use of its members (not for resale) from pharmacies. Iron Workers paid more than it

would have absent the defendants' unlawful anticompetitive scheme to prevent generic competition and was injured as a result of the illegal and wrongful conduct alleged herein. Iron Workers intends to continue purchasing QVAR and/or QVAR Redihaler and has been, and will continue to be, injured as a result of the defendants' ongoing unlawful conduct.

19. Plaintiff Utah-Idaho Teamsters Security Fund is a multiemployer health and welfare plan headquartered in Utah that provides self-funded healthcare coverage to over 3,000 employees and their family members. During the class period, as defined below, Utah-Idaho Teamsters purchased, paid, and/or provided reimbursement for some or all of the purchase price of QVAR and QVAR Redihaler for the personal and/or household use of its members, and not for resale, from pharmacies located in and/or on behalf of its members. Utah-Idaho Teamsters paid more than it would have absent the defendants' unlawful anticompetitive scheme to prevent generic entry and was injured as a result of the illegal wrongful conduct alleged herein. Utah-Idaho Teamsters intends to continue to purchase QVAR, QVAR Redihaler, and/or their generic equivalents and has been, is, and will continue to be injured as a result of the defendants' ongoing unlawful conduct.

20. Plaintiff Jacksonville Police Officers and Fire Fighters Health Insurance Trust ("Jacksonville Trust"), is a health insurance trust that provides medical coverage, including pharmacy benefits, to its members. Jacksonville Trust is organized under the laws of the State of Florida, with its principal place of business at 625 Stockton Street, Jacksonville, Florida 32204. Jacksonville Trust purchased

and/or provided reimbursement for some or all of the purchase price of QVAR Redihaler or its AB-rated generic in Florida and Indiana at supracompetitive prices during the class period and, thus, suffered antitrust injury as a result of Defendants' unlawful conduct. Jacksonville Trust intends to continue to purchase QVAR, QVAR Redihaler, and/or their generic equivalents and has been, is, and will continue to be injured as a result of the defendants' ongoing unlawful conduct.

21. Plaintiff New York State Teamsters Council Health & Hospital Fund ("New York Fund"), is a health insurance fund that provides medical coverage, including pharmacy benefits, to its members. New York Fund is organized under the laws of the State of New York, with its principal place of business at 151 Northern Concourse, Syracuse, New York 13212. New York Fund purchased and/or provided reimbursement for some or all of the purchase price of QVAR Redihaler or its AB-rated generic in New York, New Jersey, Maryland, Tennessee, Vermont, Illinois Arizona, North Carolina, and Massachusetts at supracompetitive prices during the class period and, thus, suffered antitrust injury as a result of Defendants' unlawful conduct. New York Fund intends to continue to purchase QVAR, QVAR Redihaler, and/or their generic equivalents and has been, is, and will continue to be injured as a result of the defendants' ongoing unlawful conduct.

22. Teva Pharmaceutical Industries Ltd. is incorporated under the laws of Israel, with its principal place of business in Tel Aviv, Israel.

23. Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business in Parsipanny, New Jersey. Upon information and belief,

Teva Pharmaceuticals USA, Inc. is a subsidiary of Teva Pharmaceutical Industries Ltd.

24. Teva Branded Pharmaceutical Products R&D, Inc. is a company organized under the laws of the State of Delaware with its principal place of business in Montvale, New Jersey. Upon information and belief, Teva Branded Pharmaceuticals R&D, Inc. is a subsidiary of Teva Pharmaceuticals USA, Inc.

25. Norton (Waterford) Ltd. ("Norton") is a private limited company organized under the laws of the Republic of Ireland and has its registered office in Waterford, Ireland. It is a subsidiary of Teva Pharmaceuticals Industries Ltd. Norton trades (i.e., does business) as Ivax Pharmaceuticals Ireland and Teva Pharmaceuticals Ireland.

26. Teva Pharmaceuticals Industries Ltd., Teva Pharmaceuticals USA, Inc., Teva Branded Pharmaceutical Product R&D, Inc., and Norton (Waterford) Ltd. are collectively referred to herein as the defendants, or Teva.

III. JURISDICTION AND VENUE

27. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(d) because this is a qualifying class action, as defined in § 1332(d)(1)(B); the amount in controversy stretches into the hundreds of millions, if not billions, of dollars and thus exceeds the $5 million jurisdictional threshold set forth in § 1332(d)(2); at least one plaintiff is a citizen of a different state than the defendants, and the class (comprised of citizens of states and U.S. territories) have brought suit against foreign entities, Teva Pharmaceutical Industries, Ltd. and Norton. Thus, this class action meets the criteria under both subsections (A) and (C) of § 1332(d)(2).

28. This Court also has subject matter jurisdiction under 28 U.S.C. §§ 1331 (federal question), 1337(a) (antitrust), and 15 U.S.C. § 15 (antitrust).

29. The defendants transact business within this district, and they transact their affairs and carry out interstate trade and commerce, in substantial part, in this district and/or have an agent and/or can be found in this district. Venue and personal jurisdiction are therefore appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22 (nationwide venue and personal jurisdiction for antitrust matters).

30. Venue is also appropriate within this district under 28 U.S.C. § 1391 because the defendants transacted business within this district and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district, and a substantial part of the events giving rise to the plaintiffs' claims occurred in this district. Further, the defendants reside in this district.

31. This Court also has personal jurisdiction over the defendants because the plaintiffs purchased QVAR and QVAR Redihaler products in Massachusetts. The defendants introduced their QVAR and QVAR Redihaler products into interstate commerce, knowing and intending that it would be imported, prescribed, sold, and paid for in Massachusetts. Their scheme to delay generic QVAR competition deprived patients and payors in Massachusetts of the ability to purchase affordable generic version of QVAR or QVAR Redihaler. The plaintiffs and other members of the class overpaid for the defendants' QVAR products in Massachusetts, suffered damages in Massachusetts, and will continue to suffer damages in Massachusetts. For example,

Iron Workers, which is at home in this district, overpaid for thousands of dollars of QVAR and QVAR Redihaler for the personal use (not resale) by its members.

IV. INDUSTRY BACKGROUND

32. Branded drug companies can obtain valid patents over their prescription drug products. These patents provide limited protection from generic competition by other drug companies for a fixed period—often called an exclusivity period—set by Congress.[1] Being able to protect truly novel products with patents encourages innovation and the development of new medications.

33. During this exclusivity period, brand-name drugmakers can demand very high prices for medications that cost relatively little to manufacture. Because patent protection prevents other companies from making a competing generic version of the medication, purchasers, payors, and the public must pay those very high prices.

34. Once a brand drug company's period of exclusivity expires, though, the company can no longer lawfully block generic competition. Other drug companies seeking to market generic versions of the drug—identical versions of the drug that are just as safe and effective, yet far less expensive—can enter the market. Generic drugs have saved the public more than $2.6 trillion over the past decade.

[1] In addition, to encourage drug companies to ensure their drugs are safe and effective for use in children, the FDA may grant an additional six month "exclusivity" for a drug for which a brand drugmaker has studied its safety and efficacy in children. Accordingly, if a patent claiming a drug product were set to expire on January 1, and the drug's sponsor studied the effect of the drug product on children, its lawful exclusivity period would extend to July 1.

35. The federal drug laws balance these competing interests: rewarding and incentivizing genuine innovation by brand-name drugmakers while ensuring the earliest possible availability of more affordable generic drugs.

36. They accomplish this, in part, by requiring brand-name drugmakers to submit to the FDA information about patents that claim (i) a drug's active ingredient, (ii) a drug product that includes the active ingredient, or (iii) a method of using the drug. The FDA publishes this information in a ministerial capacity, without scrutiny, in the Orange Book, so that generic companies seeking to come to market know which patents might stand in their way.

37. A would-be generic competitor must notify the brand-name drugmaker if it seeks to market a generic version of the brand-name drug before the expiration of an Orange Book listed patent for the brand drug. If the brand-name drugmaker has an objectively reasonable and good-faith reason to believe that the competitor's product would infringe a valid, enforceable patent, it can sue. By suing, the brand-name drugmaker can delay approval of the competing product for two and a half years.

38. But unscrupulous drug companies can (and do) game the system by submitting false or misleading patent information to the FDA's Orange Book—for example, by representing that a patent claims the drug when it does not. This forces a would-be competitor to give the brand company advance notice of competition; enables the brand company to sue; triggers an automatic two-and-a-half-year delay

in generic competition; and provides the opportunity for the brand-name drugmaker to settle the suit in a way that delays competition even more.

39. The defendants are just this sort of unscrupulous company.

A. The federal drug laws speed generic drug availability by (i) allowing generic drugmakers to file abbreviated drug applications and (ii) streamlining patent disputes.

40. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*. governs the manufacture, sale, and marketing of prescription drugs in the United States.

41. Before any drug may be sold in the United States, it must first be approved by the FDA. There are three types of drug applications for FDA approval—two for brand-name drugs and one for generics.

42. A manufacturer seeking to market and sell a new brand drug must submit a New Drug Application, or NDA. Typically, an NDA is submitted pursuant to § 505(b)(1) of the FDCA and must include specific and extensive data concerning the safety and effectiveness of the drug.

43. Sometimes, an application may be submitted under § 505(b)(2) if the proposed product has the same active ingredient as an already-approved product (called the reference product), but in a different amount, dose, or form. A brand-name drugmaker that files a § 505(b)(2) NDA may rely on the reference product's data rather than incurring the expense and burden of conducting clinical trials.

1. In the Hatch-Waxman Amendments, Congress created a streamlined, abbreviated approval process for generic drugs.

44. Until 1984, all drugmakers had to submit voluminous NDAs with costly and time-consuming clinical studies before they could market or sell any drug—brand name *or* generic. Because would-be generic companies intended to make their drugs available at an affordable price, clinical studies were almost always cost prohibitive. And even those companies able to shoulder that cost faced potentially ruinous liability: if their product infringed just one of the brand-name drugmaker's patents, the brand company could sue once they launched, exposing the company to astronomical litigation costs and the possibility of significant monetary damages.

45. Because of these risks, generic companies just waited until they were certain they could no longer be sued before even beginning to try to develop a much-needed generic drug. As a result, in 1983, 65% of brand-name drugs with no patent protection had no generic competition, and only 19% of non-antibiotics prescriptions were filled with generic drugs.

46. In 1984, Congress tried to address this problem by enacting the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments created a simplified pathway to approval for generic drugs.

47. Rather than requiring expensive, time-consuming clinical trials for generic drugs, the Hatch-Waxman Amendments allow a generic drug company to file an Abbreviated New Drug Application, or ANDA. In an ANDA, a generic company can establish that its product is bioequivalent to the brand-name drug (the reference-

listed drug)—meaning that the generic drug contains the same active ingredient(s) in the same amount, administered in the same form, at the same strength; and is absorbed into the body in the same way, at the same rate, and to the same extent as the brand-name drug. A showing of bioequivalence demonstrates that the generic drug has the same clinical effect as its brand-name counterpart and allows the ANDA applicant to rely on the NDA's clinical studies to prove its own drug safe and effective.

48. Drugs that are bioequivalent are also therapeutically equivalent, meaning that one may be substituted for the other. The FDA has a term for this: generic drugs that are bioequivalent to brand-name drugs are "AB-rated" to the brand-name drug.

49. Every state has adopted laws that require or permit pharmacies to substitute affordable AB-rated generic equivalents for brand-name prescriptions.

50. As a result, when an AB-rated generic drug enters the market, prices decline rapidly and sales shift quickly to the generic product. Often 80% of the market shifts to generic sales within six months after generic entry. Within a year, generic drugs capture 90% of sales, and the price drops to just 15% of the branded price.

51. To ensure that this brand-to-generic switch happens as soon as possible, the Hatch-Waxman Amendments introduced a second innovation: a streamlined process for resolving disputes over Orange Book-listed patents.

2. The Hatch Waxman Amendments streamlined patent dispute resolution.

52. The drug laws provide a way for generic companies to challenge weak or invalid drug patents without risking damages if the patents are upheld.

i. The plain language of the Hatch-Waxman Amendments limits Orange Book listings to patents that claim the drug or a method of using the drug for which the applicant submitted the application.

53. From 1983 until 2019, the FDCA required NDA applicants to submit the following to the FDA:

> the patent number and the expiration date of any patent which *claims the drug for which the applicant submitted the application* or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

54. In this provision, Congress imposed a two-part listing test; brand-name drugmakers may submit only those patents that satisfy both prongs for listing in the Orange Book.

55. First, the universe of patents that Congress contemplated in this provision is narrow. Not only must the patent claim a drug (or a method of using that drug), it must also claim the drug or a method of using the drug for which the brand drug company submitted its NDA. And it is not enough for a patent to just mention a drug for which an NDA holder submitted its NDA: it must "claim" that drug.

56. "Claim" has a specific meaning in the patent law context. A patent's "claim" is "the portion of the patent document that defines the scope of the patentee's rights." It is found in "specific, formal language recited at the conclusion of a patent 'specification,' which is the required written description of an invention . . . in a patent or patent application."

57. A mere reference to the drug for which a brand-name drugmaker submitted its application that appears elsewhere in a patent, such as the abstract or specification, is not enough to list a patent in the Orange Book. The reference to the drug for which a brand-name drugmaker submitted its NDA must appear in the claims. A patent that does not mention, much less claim, a drug cannot lawfully be submitted to the FDA for listing in the Orange Book.

58. Second, the patent must reasonably be capable of being asserted against a would-be competitor seeking to make the drug. The brand-name drugmaker must not submit a patent it knows, or should know, is invalid or unenforceable.

59. If a patent fails to satisfy either one of the statutory listing test's two criteria, a brand-name drugmaker may not submit it for listing in the Orange Book.

60. A brand-name drugmaker may obtain additional patents after NDA approval. If those patents satisfy the two-part statutory listing test, the brand-name drugmaker must submit the patents' information to the FDA once they issue.

ii. The FDA's implementing regulations limit drug patents to those that claim the drug substance or a drug product containing the drug substance.

61. In October 1994, the FDA issued a new regulation, 21 C.F.R. § 314.53, implementing Congress' two-part statutory listing test. There are three key provisions in those initial implementing regulations.

62. **First, a brand drug company cannot submit a patent unless it claims a drug substance, drug product, or method of using a drug substance or drug product**. The regulations explained which patents "claim[] the drug" within

the meaning of the statute: "*drug substance* (active ingredient) patents, *drug product* (formulation and composition) patents, and method-of-use patents."

63. The FDA reiterated what was clear from the plain language of the statute: only patents that claim the drug for which an NDA was filed may be submitted. The final rule declared that "[f]or patents that claim the drug substance, the applicant shall submit information *only* on those patents that claim the drug substance *that is the subject of the pending or approved application*, or that claim a drug substance that is the same as the active ingredient that is the subject of the approved or pending application."

64. **Second, the regulations obligate the drugmaker to identify the type of patent it is submitting**. Section 314.53(c)(1) sets forth the patent information that an NDA holder must submit to the FDA including: (i) the patent number and the date on which the patent will expire; (ii) the "type of patent, i.e., [d]rug substance (active ingredient), drug product (formulation or composition), and method-of-use"'; and (iii) the name of the patent owner or owners. During the rulemaking process, the FDA rejected commenters' suggestions that brand-name drugmakers should not be held to identifying patents as drug substance, drug product, or method-of-use patents.

65. **Third, brand-name drugmakers must submit a declaration that the submitted patent is properly listable**. To ensure that brand-name drugmakers truthfully submitted only those patents that were permitted by the statute's plain language and the explanatory text of § 314.53(b), the FDA's

regulations required that any patent submission be accompanied by a signed declaration:

> The undersigned declares that Patent No. ____ covers the formulation, composition, and/or method of use of (*name of drug product*). This product is (*currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act*) [or] (*the subject of this application for which approval is being sought*): _____.

66. Several industry commenters tried to deter the FDA from implementing these safeguards against untruthful patent submissions. For example, one suggested deleting the language that required a brand-name drug company to swear that a patent claimed the drug substance, drug product, or method of use "and replacing it with a general certification that the patents listed by the applicant contain claims with respect to which the applicant could reasonably assert a claim of infringement against a person engaged in the unlicensed manufacture, use, or sale of the drug for which the application was submitted."

67. The FDA rejected the comment, noting that the statute's plain text imposed the limitation that the submitted patent must "claim[] the drug" or a method of using the drug, not just that the patent may be asserted. This, the agency said, coupled with the fact that the "FDA lacks patent law expertise" warranted a two-part certification that tracked the two-part statutory listing test.

68. Other commenters suggested that the FDA, not drugmakers, should evaluate whether a submitted patent meets the statutory listing test. The FDA rejected these comments, too. It explained that the "FDA does not have the expertise to review patent information" and "its scarce resources" would be better utilized in

reviewing applications rather than reviewing patent claims. And it explained that "the declaration requirements under § 314.53(c), as well as an applicant's potential liability if it submits an untrue statement of material fact, will help ensure that accurate patent information is submitted."

69. This new regulation, § 314.53, went into effect on November 2, 1994.

iii. In 2003, the FDA amended its Orange-Book-listing regulations in response to improper listings.

70. On June 18, 2003, the FDA amended § 314.53 of its regulations "to help ensure that NDA applicants submit only appropriate patents," and to prevent brand-name drugmakers from "submitting patents that do not meet the statutory and regulatory requirements."

71. The FDA did not change the key provisions of its rules: it reiterated that the statute imposed a two-part test requiring applicants to submit only a "patent that claims the drug or a method of using the drug that is the subject of the new drug application . . . *and* with respect to which a claim of patent infringement could reasonably be asserted" against a would-be competitor.

72. There are four key clarifying provisions in the new rule and the FDA's accompanying commentary.

73. **First, the FDA removed any ambiguity as to what it meant for a patent to claim the "drug product."** The new rule provided a very clear explanation of how an NDA holder could determine whether a patent "claims the drug" within the meaning of the statute: Read the FDA's regulations.

74. Under § 314.53, "[f]or patents that claim a drug product, the [NDA holder] shall submit information *only* on those patents that claim a drug product, *as is defined in § 314.3*, that is described in the pending or approved application."

75. Section 314.3 provides the definitions that apply to Part 314 of the FDA's regulations, including the Orange Book listing regulations.

76. It defines "drug substance" as "an active ingredient that is intended to furnish pharmacological activity or other direct effect . . . ."

77. It defines "drug product" as "a finished dosage form, e.g., tablet, capsule, or solution, *that contains a drug substance*, generally, but not necessarily, in association with one or more other ingredients."

78. The definition of drug product incorporates the defined term "drug substance." Putting the two definitions together, then, the FDA defines "drug product," for purposes of its listing regulations, as:

> a finished dosage form, e.g., tablet, capsule, or solution, that contains ["an active ingredient that is intended to furnish pharmacological activity or other direct effect"], generally, but not necessarily, in association with one or more other ingredients.

79. In the Orange Book listing regulations, therefore, the FDA made it clear: only those patents that claim the drug substance, either on its own or in combination with other ingredients, may be submitted for listing in the Orange Book.

80. A patent which claims some aspect of an approved drug *in combination with* the drug substance may be listed. But a patent that claims that aspect alone, and *not in combination* with the active ingredient, must *not* be listed.

81. For example, a patent that claims only an *in*active ingredient does not meet the definition of a drug product patent and must not be submitted to the Orange Book. But a patent that claims the inactive ingredient in combination with the drug's active ingredient could qualify as a "drug product" patent.

82. Likewise, a patent that claims only a controlled-release tablet coating must not be listed submitted for listing in the Orange Book. But a patent that claims the drug coating in combination with the drug's active ingredient would be a "drug product" patent which should be submitted for listing in the Orange Book for a drug including such coating.

83. And a patent that claims only a device used to deliver the active ingredient (such as an autoinjector, an injector pen, or an inhaler) must not be submitted for listing in the Orange Book. Only if the patent claimed the device *in combination with the active ingredient* could the patent lawfully be submitted.

84. Second, the FDA's existing rules made clear that patents claiming a molecule other than the active ingredient must not be submitted. In its 2003 rulemaking, the FDA addressed uncertainty as to whether patents should be submitted for listing if they claimed a polymorphic form of an active ingredient.

85. Some commenters urged the FDA to get even more specific about what patents must not be submitted. This included a comment suggesting that the FDA impose "[s]pecific exclusions" of other categories of patents, such as "patents for forms of the active ingredient not marketed, such as acids, freebases, salts, and isomers."

86. The FDA declined to make this change—but not because patents claiming an acid, freebase, salt, or isomer of an active ingredient were listable. The agency "believe[d] the patent information requested" (i.e., the requirement that the NDA holder identify whether the patent claimed the drug for which it submitted its NDA) "is sufficient to ensure only eligible patents are submitted for listing."

87. **Third, the FDA *rejected* suggestions that device patents should be listed in the Orange Book**. The FDA confirmed in its rulemaking that "patents claiming packaging . . . must not be submitted for listing in the Orange Book," because "[s]uch packaging and containers are distinct from the drug product and thus fall outside of the requirements for patent submission."

88. Nevertheless, some commenters argued that "integral" devices such as "metered dose inhalers" "should be submitted and listed." The FDA said no, politely. It explained:

> [W]e have clarified the rule to ensure that if the patent claims the drug product *as defined in § 314.3*, the patent must be submitted for listing.
>
> Section 314.3 defines a "drug product" as "* * * a finished dosage form, for example tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." The appendix in the Orange Book lists current dosage forms for approved drug products. The list includes metered aerosols, capsules, metered sprays, gels, and pre-filled drug delivery systems. *The key factor is whether the patent being submitted claims the finished dosage form of the approved drug product.*

89. The FDA made clear: the relevant question is whether a patent claims "a finished dosage form . . . that contains a drug substance," not whether it claims

some "integral" aspect of the drug product. It *rejected* the idea that it was enough for a patent to claim just a device, even if that device was "integral" to using the drug.

90. **Fourth, the FDA strengthened brand-name drug companies' obligation to submit only truthful, accurate information**. The FDA updated the declaration brand-name companies are required to make when submitting a patent for listing. It did so by providing a standardized form for patent submissions, called the FDA Form 3542 (the "Patent Listing Form").

91. The Patent Listing Form requires companies to identify a patent by the patent number, issue and expiration dates, and owner, then asks a series of questions to guide the NDA holder in determining whether the patent is listable.

92. Question 2.1 asks whether the patent "claim[s] the drug substance that is the active ingredient in the drug product described in the approved NDA or supplement." If the NDA holder answers "no," the form warns, the "FDA will not list the patent in the Orange Book as claiming the drug substance[.]"

93. Question 3.1 asks whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*"; if the NDA holder answers "no," the "FDA will not list the patent in the Orange Book as claiming the drug product[.]"

94. And Question 4.1 asks whether the patent "claim[s] one or more methods of using the approved drug product." If the answer is "no," then the "FDA will not list the patent in the Orange Book as claiming the method of use[.]"

95. The FDA reiterated in its rulemaking that its "patent listing role remains ministerial."

96. In reviewing the Patent Listing Form, the FDA does not ensure that a brand-name drugmaker's answers are truthful; it merely ensures that the company has provided answers that, *if accurate*, would entitle the company to list the patent in the Orange Book.

97. Instead, the agency strengthened the language of the declaration that the brand-name drugmaker's representative must sign to ensure compliance:

> The undersigned declares that this is an accurate and complete submission of patent information for the NDA or supplement approved under Section 505 of the Federal Food, Drug and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 C.F.R. 314.53. *I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.*
>
> Warning: a willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

iv. Despite the plain language of the FDCA and the FDA's regulations, brand-name drugmakers continued to seek ways to list device-only patents.

98. Even after the FDA clarified that device-only patents could not be submitted to the Orange Book, brand-name drugmakers kept trying to convince the FDA to allow them to submit for listing patents that claimed a device, not a drug.

99. The FDA provides a number of ways for companies to seek changes to existing regulations. One is a citizen petition directed at requesting changes to how a specific drug or class of drugs is treated by the FDA. Another is a request for an advisory opinion. Both types of petitions constitute advocacy to *change* what the drug

laws and regulations permit or require: sponsors do not (in good faith) ask the FDA to enact a policy it has already enacted.[2]

100. Between 2005 and 2012, four brand-name drugmakers submitted advisory opinion petitions to the FDA concerning the listability of device patents.

101. Each petitioner acknowledged that the FDA could have expressly required the listing of "integral" device patents but did not. And each recognized that "[t]he key factor is whether the patent being submitted claims the finished dosage form of the approved drug product" as defined in 21 C.F.R. § 314.3.

102. Most of the petitioners acknowledged that FDA draft guidance concerning combination products—one concerning nasal aerosol sprays and one concerning inhalers—defined a "drug product" *not* as just the device alone, but as the formulation "together" with the device "collectively."

103. Each admitted that the regulations do not require brand-name drugmakers to list patents claiming just a device alone:

- **GSK**: "FDA *has yet to be explicit* on the question of whether the listing requirement applies to patents that . . . do not claim the drug substance . . . in conjunction with the drug delivery device[.]"
- **AstraZeneca's First Petition**: "FDA *has not . . . directly addressed* whether patents directed to . . . inhalers . . . that do not recite the

[2] Some drugmakers do to delay competition. Because the FDA defers approving an ANDA until it has resolved all petitions affecting that application, brand-name drugmakers have exploited the petitioning process to thwart competition. Often, the petitions provide no scientific basis for the changes requested. "The Generic Drug Maze: Speeding Access to Affordable Life-Saving Drugs," Senate Hearing 109-685, July 20, 2006 (former head of the Office of Generic Drugs Gary Buehler: "very few"—just 3 out of 42—citizens petitions "presented any data or analysis" that would support a change in the FDA's rules or policies); *Antitrust Concerns and the FDA Approval Process*, Statement of Scott Gottlieb, M.D., Comm'r of Food & Drugs before the House Committee on the Judiciary, Subcommittee on Regulatory Reform, Commercial and Antitrust Law (Jul, 27, 2017) (explaining many petitions are "intended primarily to delay the approval of competing drug products" rather than to raise "valid scientific or public health issues").

approved active ingredient or formulation should be listed in the Orange Book."

- **AstraZeneca's Second Petition**: "*FDA has not directly addressed the question* [of] whether the listing requirement applies to patents [that] disclose but do not claim, or neither disclose nor claim, the active ingredient or formulation of the approved drug product."

- **Forrest**: "[G]uidance regarding compliance with the listing requirement is not clear when the patent claims a drug delivery device integral to the administration of the active ingredient but does not recite the active ingredient. . . . *[N]either the rules nor past guidance from the FDA address the issue . . . explicitly*[.]"

- **Novo**: "FDA's distinction between pre-filled drug delivery systems and product packaging *remains unclear* . . . ."

104. In other words, each petitioner acknowledged that there was no concrete regulatory imperative to list a patent claiming a device alone.

105. And each petitioner implicitly admitted the true reason for their requests: the desire to delay competition. None of them was express about it, but each noted (favorably) that listing device-only patents would enable a brand company to sue a would-be competitor and trigger an automatic 30-month delay of competition.

106. In sum, the brand-name drugmakers (a) acknowledged the FDA had already rejected suggestions that device-only patents be listed in the Orange Book; (b) admitted that the FDA had admonished that the "key factor" was whether a patent met § 314.3's definition of a drug product; (c) admitted that the "drug product" for a combination patent was the formulation "together" with the device "collectively"; (d) conceded that the regulations did not require listing device-only patents; and (e) betrayed their intent to leverage device patents to delay competition.

107. None of the petitioners offered an interpretation of the existing rules that would permit listing device-only patents; instead, they each argued the FDA should change its rules. None provided any reasoned basis for this change—other than their desire to leverage those patents to delay competition. But the fact that the brand-name drugmakers wanted to bottleneck competition with device patents does not mean the law or the regulations permitted them to do so. Nor does that desire make it reasonable to violate the FDA's clear regulations.

108. The FDA—having already addressed the issue—did not grant any of these petitions. In fact, it declined to respond "due to the need to address other Agency priorities." The FDA is a resource-, budget-, and time-constrained agency. It does not divert resources from drug approvals to address issues squarely governed by existing rules—particularly on patent-law issues, on which the FDA lacks expertise.

v. In 2020, Congress cracked down on continued listing abuse.

109. In 2019, the Orange Book Transparency Act was introduced in the U.S. House of Representatives. A House Committee report cited, among the reasons for the bill, the fact that "some branded drug manufacturers . . . are submitting patents . . . for the purpose of blocking generic competition."

110. On January 5, 2021, it became law. It amended the FDCA's listing provision to reiterate that *only* drug substance, drug product, and method-of-use patents should be submitted to the Orange Book. It required submission of:

> (vii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the

> patent engaged in the manufacture, use, or sale of the drug, and that
>
> > (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or
> >
> > (II) claims a method of using such drug for which approval is sought or has been granted in the application.

vi. Brand-name drugmakers, including Teva, still tried to change the rules.

111. In 2020, the FDA solicited comments from the public regarding how to strengthen its Orange-Book listing regulations.

112. On August 30, 2020, Teva weighed in.

113. In its comment, it misrepresented the FDA's 2003 rulemaking process, claiming that the

> FDA itself has explained: " . . . The key factor is whether the patent being submitted [for listing] claims the finished dosage form of the approved drug product," since those aspects of the approved drug product "are 'integral' to the drug product [and] require prior FDA approval" in light of their potential impact on the safety and effectiveness of the approved NDA product.

114. That is not what the FDA said—in fact, part of it is not even the FDA's words. Rather brand drugmaker *commenters* said that patents should be listed if they "are 'integral' to the drug product [and] require prior FDA approval"—and the FDA said "*no*." The FDA clarified that *instead of* the "integral to" test posed by the commenters, "[t]he *key factor* is whether the patent being submitted [for listing] claims the finished dosage form of the approved drug product."

115. To avoid any ambiguity, here is the full passage from the 2003 Rulemaking (with Teva's selective, misleading, and carefully arranged quotations bolded):

> (Comment 3) Most comments agreed that patents claiming packaging should not be submitted for listing. However, *some comments stated* that patents claiming devices or containers that **are "integral" to the drug product or require prior FDA approval** should be submitted and listed. These comments distinguished between packaging and devices such as metered dose inhalers and transdermal patches, which are drug delivery systems used and approved in combination with a drug.
>
> (Response) We agree that patents claiming a package or container must not be submitted. Such packaging and containers are distinct from the drug product and thus fall outside of the requirements for patent submission. However, we have clarified the rule to ensure that if the patent claims the drug product as defined in § 314.3, the patent must be submitted for listing. Section 314.3 defines a "drug product" as "* * * a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." The appendix in the Orange Book lists current dosage forms for approved drug products. The list includes metered aerosols, capsules, metered sprays, gels, and pre-filled drug delivery systems. **The key factor is whether the patent being submitted claims the finished dosage form of the approved drug product**.

116. Teva argued for the adoption of this "integral to" test that the FDA refused to adopt during the 2003 rulemaking—and refused to adopt in response to five other brand-name drugmaker's petitions. Teva implicitly admitted that regulations did *not* require listing device-only patents in the Orange Book, arguing only what the rule "should" or "ought" to be:

- "Teva generally believes that all patents which claim an integrated device component of an approved NDA product . . . *should be* listed in the Orange Book."

- "[W]e believe that patents *should be* listed in the Orange Book so long as: (1) the patent-at-issue legitimately claims an integrated device component of an approved NDA product or a method of using such a constituent part; and (2) FDA directly reviewed that integrated device component in connection with, and as a condition of approving, the listed NDA product."

- "The dispositive question *ought to be* whether FDA directly reviewed an integrated device component in connection with . . . the listed NDA product in its proposed dosage form . . . ."

- The "question we believe *should be* dispositive to the patent-listing questions at issue here" is "whether . . . the claimed-by-patent integrated device constituent of a combination product . . . was reviewed by FDA . . . ."

117. And Teva argued that any change the FDA made to its Orange-Book listing rules "should apply only prospectively—that is, after the effective date of any new regulations"—meaning that if a patent were improperly listed under the now-existing rules, any future rule change would not excuse that improper listing.

vii. The statutory and regulatory rules for Orange Book listings provide a very simple rule.

118. These straightforward statutory and regulatory limitations on what patents may be listed as drug product or drug substance patents can be distilled to a very simple two-part rule.

119. First, a patent can only be listed if it "claims the drug for which the applicant submitted the application or . . . a method of using such drug." That means:

- If a patent does not mention, let alone claim, the drug's active ingredient (or a method of using that drug's ingredient), then it must not be submitted for listing.

- If a patent merely mentions the drug's active ingredient in the specification, but does not include the active ingredient as a limitation in a claim, then it must not be submitted.

- If a patent claims an active ingredient for a drug other than the one that is the subject of the brand-name drugmaker's NDA, then it must not be submitted.

120. Second, if a patent passes the first step of this test, the patent must be one that "could reasonably be asserted" against a would-be competitor. A brand-name drugmaker must not submit a patent that it knows is invalid or unenforceable.

121. If a patent does not pass both criteria under the listing test, it must not be listed in the Orange Book.

122. Teva broke this simple rule more than a dozen times over.

3. The Hatch-Waxman Amendments require would-be generic companies to address each Orange-Book-listed patent.

123. The notice provided by brand-name drugmakers to would-be competitors by submitting patents to the Orange Book is not a one-way street. In exchange, the Hatch-Waxman Amendments require would-be competitors to notify the brand-name drugmaker of any patents it believes are invalid or not infringed.

124. For each patent listed in the Orange Book, a would-be generic competitor must include in its ANDA one of four certifications:

> (I) No patents have been listed in the Orange Book;
>
> (II) Any listed patents have expired;
>
> (III) The would-be competitor will wait for a patent's expiration before marketing its competing product; or
>
> (IV) A listed patent "is invalid or will not be infringed by the manufacture, use, or sale" of the competitor's product.

125. If an ANDA applicant makes a certification under one of the first two paragraphs, then no patent will delay generic competition. At the other extreme, a certification under the third paragraph (known as a paragraph III certification) means the generic applicant will have to wait until the relevant patent has expired.

126. The fourth option, known in the industry as a "paragraph IV certification," provides a middle ground—a means to speed generic entry even when one or more patents are listed in the Orange Book. A generic competitor must notify the brand-name drugmaker of any paragraph IV certifications in its ANDA and provide a "detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." This serves "to give notice, if necessary, to the patent holder so that any legal disputes regarding the scope of the patent and the possibility of infringement can be resolved as quickly as possible."

127. For method-of-use patents, there is a fifth option: a would-be competitor can file what is known as a "section viii carveout." Under Section 505(j)(2)(A)(viii) of the FDCA, a would-be generic competitor can submit a statement averring that it will not market the drug for one or more methods of use claimed by a listed patent:

> [I]f with respect to the listed drug referred to in [section 505(j)(2)(A)(i)] information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, [the ANDA must contain] a statement that the method of use patent does not claim such a use.

If an ANDA applicant files a section viii statement, the patent claiming the protected method of use cannot bar approval of the ANDA.

4. Hatch-Waxman patent certifications may lead to litigation.

128. Often a generic company that provides a brand-name drugmaker with a paragraph IV notification will make an Offer of Confidential Access, allowing the brand-name drugmaker to review portions of the ANDA to assess infringement.

129. Filing an ANDA may provoke litigation. To incentivize generic companies to bear this litigation burden, Congress provided an incentive. The first generic drug maker to file a substantially complete ANDA containing a paragraph IV certification is eligible for 180 days of marketing exclusivity when it launches.

130. This first generic drugmaker is referred to as the "first-filer," and the exclusivity it is eligible for is called the first-filer's six-month or 180-day exclusivity. "Exclusivity," however, is a bit of a misnomer. The FDCA prohibits the FDA from approving other *ANDAs* during that 180-day period, but a brand-name drugmaker may sell or license a generic product, called an "authorized generic," under its NDA.

131. If a first-filer certifies that it will wait until all Orange-Book listed patents expire, it does not get the six-month exclusivity. That is, the exclusivity is intended to serve as an incentive to try to bring generic drugs to market *before* all Orange-Book listed patents expire.

132. But a generic drug company cannot race to be the first-filer and then sit on its exclusivity, bottlenecking the market indefinitely. The FDCA provides ways in which a first-filer may forfeit exclusivity. For example, a first-filer forfeits its exclusivity if it fails to launch its product within 75 days after the later of either (i) ANDA approval or (ii) a court decision finding, or a settlement admitting, that the patents blocking the first-filer from market entry are invalid or not infringed.

133. A 180-day exclusivity is incredibly valuable to a generic applicant: automatic substitution laws and the fact that no other ANDAs may be approved during that time allows the first-filer to reap substantial profits. As the Supreme Court has recognized, "this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars'" to the first-filer.

5. If a brand-name drugmaker has a reasonable, good-faith basis to believe its patents are valid and would be infringed, it may sue.

134. When Congress enacted the Hatch-Waxman Amendments, it also amended the patent laws to state that filing an ANDA constitutes "technical" patent infringement and provides the brand company standing to sue.

135. If a brand-name drugmaker with a reasonable and good-faith belief that an ANDA product infringes one or more valid patents sues within forty-five days of receiving a paragraph IV notification, the Hatch-Waxman Act imposes an automatic stay preventing the FDA from granting final approval to the ANDA until (a) the passage of 30 months or (b) a court decision finding that the patent is invalid or not infringed by the ANDA product, whichever happens sooner. A section viii carveout, however, does not trigger this mechanism, and cannot delay ANDA approval or the generic competition that follows.

136. If an ANDA is ready for approval before one of those conditions occurs, the FDA may grant "tentative approval." Tentative approval is warranted when an application satisfies all scientific and procedural conditions to final approval, but the FDA may not grant final approval due to the 30-month litigation stay.

B. Brand-name drug makers can enforce patents that are not listed in the Orange Book.

137. Until Congress enacted the Hatch-Waxman Amendments, there was no streamlined patent resolution process: there was no centralized repository listing relevant patents, no paragraph IV certification process, and no ability for brand-name drugmakers to sue before a competitor launched the product. Instead, brand-name drugmakers had to wait to sue a would-be generic competitor until that competitor actually launched its generic product.

138. This is how brand-name drugmakers defended their intellectual property for years. And it is how every owner of every other type of intellectual property—from blenders to computers, from automobiles to devices—protects their non-drug-substance inventions.

139. The Hatch-Waxman Amendments created a special procedure specifically for patents claiming a drug substance, a drug product containing a drug substance, or a method of using a drug substance or product. It did not eliminate the right of a brand-name drugmaker to defend inventions *other* than a drug substance, drug product, or method-of-use through ordinary patent-law principles. A brand-name drugmaker seeking to defend a device patent, therefore, may still sue once a competitor launches a product that it believes infringes that device patent.

C. Generic-drug availability translates into substantial savings for payors and patients.

140. When only a brand-name drug is available in the market, the cost of the medicine is very high. But that cost shrinks as generic drugs become available.

141. The launch of even one generic version of a drug translates to substantial savings. As shown by economic research, the first manufacturer to launch a generic version of a drug prices its product just slightly below the price of the brand-name counterpart. State substitution laws requiring or permitting substitution of an AB-rated generic drug for a brand-name drug lead to a rapid shift in the market away from the brand-name drug and to the generic drug, even though there is only a slight discount on price.

142. According to the FTC and FDA, the greatest price reduction occurs when a second generic competitor enters the market. Because the brand-name drugmaker rarely drops its price to match the first-filer's price, the first-filer does not face price competition while it is alone in the market. When a second competitor enters, the generic companies compete on price. This drives prices down significantly: the launch of a second generic product results in a price reduction of approximately 50%.

143. And once more generic drugs are allowed to enter the market, the price reduction can reach 85% or even more. Typically, in a fully "genericized" market, prices are close to marginal manufacturing costs.

D. Brand companies seeking to unlawfully prolong their monopoly have developed ways to abuse the Hatch-Waxman system and leveraged them to delay affordable generic drugs.

144. For as long as Congress has sought to speed the availability of affordable generic medications, brand-name drugmakers have frustrated those efforts.

1. Product hops

145. One such tactic is called "product hopping," which undermines the procompetitive, pro-generic, and pro-affordability aims of states' generic substitution laws.

146. Here is how a product-hopping scheme works. A brand-name drugmaker knows that, when a would-be generic competitor gains FDA approval for the brand-name drugmaker's drug, it will quickly lose market share and profits to generic market entrants. To thwart that risk, the brand-name drugmaker makes minor (usually immaterial) changes to a drug product, such as a change to the marketed dosages or to the form of the drug (i.e., changing the drug from a capsule to a tablet). Then it takes steps to destroy the market for the original formulation.

147. There are two kinds of product hops: "soft switches" and "hard switches."

148. In a soft-switch, a brand-name drugmaker leaves the original formulation on the market, but drives physicians to prescribe the new formulation.

149. In a hard-switch product hop, a brand-name drugmaker removes the original formulation from the market entirely. This ensures, with absolute certainty, that no physician can write a prescription for the old brand-name drug formulation, and that absolutely no generic substitution can occur at the pharmacy counter.

150. Product hops work because a generic drug can only be substituted for a brand-name drug prescription if the two products are AB-rated to one another. A generic company's product, designed to be AB-rated to the original, pre-hop, product is not AB-rated to the tweaked post-hop formulation. A would-be competitor could

switch its formulation to meet the characteristics of the hopped product—but not without redesigning its product and restarting the FDA approval process.

2. Wrongful Orange Book listings

151. Another tactic deployed by brand-name drug companies to exploit the Hatch-Waxman framework and delay competition is wrongful Orange Book listings.

152. In creating the streamlined patent resolution process outlined above, the FDA struck a careful balance. Brand-name drugmakers benefit from asserting their intellectual property before a competing generic drug is launched and having two-and-a-half years to resolve good-faith patent disputes. Generic companies benefit from having a resource to identify drug patents that may block their drug product and a means of addressing disputes without risking damages.

153. But this trade-off comes with risks. As one commenter has noted: "Orange Book listing elevates every patent as a potential source of delay to generic competition," because listing a patent gives the brand-name drugmaker "almost automatic injunctive relief for even marginal infringement claims."

154. Brand-name drugmakers have weaponized this process. Listing a patent in the Orange Book that does not satisfy the two-part statutory listing test forces would-be competitors to make a certification to the patent (even though the patent does not belong in the Orange Book and should require no such certification). If the generic company makes a paragraph IV certification, the brand-name drugmaker gets to sue and trigger an automatic two-and-a-half-year delay in competition.

155. In other words, a brand-name drugmaker that improperly lists patents in the Orange Book can trigger an almost automatic two-and-a-half-year delay in

competition. That is two-and-a-half years of additional monopoly profits gained by submitting to the Orange Book a patent that does not satisfy the two-part listing test.

3. Sham litigation

156. Hatch-Waxman confers standing on a brand-name drugmaker to sue after receiving a paragraph IV notice from a would-be generic competitor. But that standing does not carry with it the right to file a frivolous suit.

157. It is incumbent upon litigants not to bring cases or make arguments that they know are meritless, or that they are pressing in bad faith. This includes brand-name drugmakers: they may not bring sham litigation.

158. Litigation is a sham if a reasonable person standing in the plaintiff's shoes would not expect there is a basis to file the suit, and the suit was brought to thwart competition. In the context of pharmaceutical Hatch-Waxman litigation, this means that a patent infringement suit is a sham if no reasonable brand-name drugmaker would reasonably expect there was a basis for bringing a Hatch-Waxman action , and if an NDA holder brought the suit for the purpose of delaying generic competition.

159. But some brand-name drugmakers do just that. Brand-name drugmakers know they cannot access the automatic two-and-a-half-year delay in generic approval unless they sue. And so some sue, regardless of the objective merit of that suit, just to delay competition.

160. There are at least two ways in which a Hatch-Waxman litigation may be objectively baseless.

161. First, Hatch-Waxman litigation may be a sham if a brand-name drugmaker sues over a patent that a reasonable drugmaker knows or should know is (a) invalid or unenforceable, or (b) not infringed by the would-be competitor's product.

162. Second, Hatch-Waxman litigation may be a sham if the brand-name drugmaker sues over a patent that a reasonable drugmaker would have or should have known was improperly listed in the Orange Book.

163. If a brand-name drugmaker brings a suit over a patent that a reasonable company would know was (a) invalid, unenforceable, or not infringed by a competitor, or (b) improperly listed in the Orange Book—and if its motivation for doing so was to delay or frustrate competition—then the litigation is a sham.

4. Reverse payment agreements

164. Hatch-Waxman litigation creates potential for delays in another way. A litigation, once filed, must be resolved. Most commonly, Hatch-Waxman litigation ends in a settlement—litigation all the way to final judgment is exceedingly rare.

165. In a lawful Hatch-Waxman litigation settlement, the brand-name drugmaker and generic drugmaker reach consensus about the strengths or weaknesses of their litigation positions and the likelihood that the patent or patents will be upheld as valid and infringed. The brand-name drug maker then gives the generic competitor a license to enter on a specific date that reflects the brand's chances of success. So, for example, if there are ten years left on a patent's term, and a brand-name drugmaker has a 40% chance of defending its patents, it would provide its challenger with a license to enter the market after four years. Usually no money

exchanges hands, in either direction, in a lawful patent-term split settlement.[3] As the FTC has explained, "[i]n light of the uncertainties facing parties at the time of settlement, it is reasonable to assume that an agreed-on entry date, without cash payments, reflects a compromise of differing litigation expectations."

166. But greedy drug companies seeking to forestall competition and preserve monopoly profits have designed a different settlement structure: a "reverse-payment" or "pay-for-delay" settlement. In a reverse payment settlement, a brand-name drugmaker plaintiff pays a would-be-competitor defendant "to respect its patent and quit its patent invalidity or noninfringement claim." A "payment" to a competitor "in return for staying out of the market" unlawfully prolongs a patentee's monopoly.

167. For example, take the hypothetical example of a brand-name drugmaker with a drug worth $1 billion per year; it knows that, once a generic version of its drug becomes available, it will quickly lose 85% of those profits, or $850 million a year. Since a generic is sold at a much lower cost than the brand-name drug, a would-be generic competitor may expect to make $150 million a year selling the drug. In a typical, if simplified, pay-for-delay deal, the brand-name drugmaker might pay that generic competitor $200 million to settle the litigation and delay entering the market by one year: the brand preserves $600 million in monopoly profits that it would have

[3] A brand-name drug company *may*, but need not and does not always, pay the generic competitor a small sum reflecting saved litigation expenses.

otherwise lost to generic competition; and the generic company collects more than it could have had it launched and sold its product.

168. As the FDA has explained, when a "patentee seeks to induce [a] generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market," "the patentee and the challenger gain; the consumer loses."

169. The "payment" in a reverse payment may be a misnomer: brand-name drugmakers cannot simply hand over a bag of cash to a would-be competitor. Instead, the payment drug companies executing a pay-for-delay agreement disguise the payment in opaque contractual terms. Common forms of reverse-payment deals include a "no-authorized-generic agreement"; a royalty payment that vanishes if another generic enters the market; or an "acceleration clause" in which a brand-name drugmaker promises to thwart later-filing generic applicants' efforts to bust the first-filer's exclusivity.

V. FACTUAL BACKGROUND

170. Eight percent of the U.S. population suffers from asthma.

171. Asthma is a treatable, but potentially deadly, condition in which the airways in a person's lungs constrict, causing coughing, wheezing, and shortness of breath. Sometimes, an acute asthma attack, if not quicky treated, can cause death. So patients with asthma depend on having access to effective medications that they know will prevent or stop an asthma attack.

A. QVAR was an expensive brand-name asthma medication.

172. QVAR was a brand-name asthma medication sold by Teva since at least the mid-2000s. It contained the drug substance beclomethasone dipropionate together with an HFA (or hydrofluoroalkane), and came in two strengths: 40 mcg and 80 mcg.

173. Neither Teva nor Norton invented the first metered dose inhalers, the first dose counters for inhalers, or even the active ingredient in QVAR.

1. 3M, not Teva or Norton, invented QVAR.

174. Beclomethasone dipropionate is a very old drug: it was first approved by the FDA in 1972. The original beclomethasone dipropionate patent is long expired.

175. Multiple types of beclomethasone dipropionate have been approved over the years, in addition to QVAR's beclomethasone dipropionate, such as beclomethasone dipropionate monohydrate.

176. Beclomethasone dipropionate is a corticosteroid—a diester of beclomethasone.

177. Beclomethasone dipropionate is not a polymorph of beclomethasone.

178. Beclomethasone is not an active ingredient approved by the FDA.

179. Beclomethasone dipropionate is not the same drug substance as beclomethasone dipropionate monohydrate.

180. Beclomethasone dipropionate is not the same drug substance as beclomethasone.

181. In 1995, the Minnesota Mining and Manufacturing Co. (more commonly known as 3M) filed an application for an aerosolized version of beclomethasone dipropionate containing a hydrofluoroalkane.

182. On July 7, 1998, the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,776,432 (the '432 patent), entitled "Beclomethasone solution aerosol formulations."

183. The '432 patent had one independent claim:

> An aerosol formulation comprising a therapeutically effective amount of beclomethasone 17,21 dipropionate, a propellant comprising a hydrofluorocarbon selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane, and a mixture thereof, and ethanol in an amount effective to solubilize the beclomethasone 17,21 dipropionate in the propellant, the formulation being further characterized in that the beclomethasone 17,21 dipropionate is dissolved in the formulation, and that the formulation is free of any surfactant.

184. The '432 patent had 11 dependent claims, each varying the details of the invention in claim 1, such as the percent by weight of beclomethasone dipropionate, the amount of ethanol, or which of the hydrofluorocarbons was selected.

185. The '432 patent expired July 7, 2015.

2. 3M, not Teva or Norton, incurred the expense or burden of obtaining FDA approval for QVAR.

186. 3M, not Teva nor Norton, sought and obtained FDA approval to make, market, and sell QVAR.

187. The active ingredient of QVAR is beclomethasone dipropionate HFA.

188. 3M filed its QVAR NDA (NDA number 20-911) on May 11, 1998. It filed a § 505(b)(2) NDA, relying for approval on studies performed on a different asthma drug. Whereas 3M sought approval for a drug containing the drug substance beclomethasone dipropionate *HFA*, it depended for approval on studies performed for a different drug containing a different drug substance, beclomethasone dipropionate *CFC*.

189. The FDA approved QVAR on September 15, 2000, with an indication for maintenance treatment of asthma—i.e., not to treat an asthma attack, but to prevent an attack from happening. It approved QVAR for use in, and for sale together with, a metered dose inhaler, sometimes referred to as an MDI.

190. When QVAR was approved, it was the only inhaled asthma product on the market that did not contain chlorofluorocarbons, or CFC. And it delivered the active ingredient, beclomethasone dipropionate, in particles one third the size of the particles delivered in other asthma products, meaning it would disperse through a patient's airways differently than other inhaled asthma products.

191. These characteristics differentiated QVAR from other asthma products.

3. After winning FDA approval, 3M submitted five patents for listing in the Orange Book—even though two of the patents did not claim QVAR.

192. Beclomethasone dipropionate first appeared in the 10th Cumulative Supplement of the 20th Edition of the Orange Book.

193. As the FDA noted during its 2003 rulemaking, "The appendix in the Orange Book lists current dosage forms." Each listed product, then, identifies the dosage form of that product.

194. When QVAR was first listed in the Orange Book, the product was characterized as a metered aerosol. At all relevant times, QVAR was listed in the Orange Book as a metered aerosol.

195. In its NDA, 3M identified three patents that it said claimed QVAR. Upon approval, 3M submitted those three patents for listing in the Orange Book under the entry for QVAR, along with two more.

196. First, 3M identified U.S. Patent No. 5,605,674 (the '674 patent), entitled "Medicinal aerosol formulations," in its QVAR application. The PTO issued the '674 patent on February 25, 1997.

197. It contained one claim. "Beclomethasone dipropionate" does not appear within this claim.

198. The '674 patent does not claim beclomethasone dipropionate.

199. Because the '674 patent does not contain a claim that includes beclomethasone dipropionate as a claim element, it does not claim either the drug substance beclomethasone dipropionate or a drug product "that contains" beclomethasone dipropionate.

200. The '674 patent expired on February 25, 2014.

201. The second patent 3M identified in its QVAR NDA as claiming QVAR is U.S. Patent No. 5,695,743 (the '743 patent) entitled "Medicinal aerosol formulations."

202. The PTO issued the '743 patent on December 9, 1997. It contained one independent claim and four dependent claims.

203. The '743 patent expired July 6, 2010.

204. The third patent identified by 3M was U.S. Patent No. 5,683,677 (the '677 patent), entitled "Medicinal aerosol formulations."

205. The PTO issued the '677 patent on November 4, 1997. It contained one independent claim and two dependent claims.

206. "Beclomethasone dipropionate" does not appear within any of these claims.

207. The '677 patent does not claim beclomethasone dipropionate.

208. Accordingly, the '677 patent does not claim either the drug substance beclomethasone dipropionate or a drug product "that contains" beclomethasone dipropionate.

209. The '677 patent expired on November 4, 2014.

210. Following FDA approval, 3M caused these three patents to be listed in the Orange Book. Additionally, it submitted the '432 patent, and a fifth patent, U.S. Patent No. 5,766,573 (the '573 patent) in the Orange Book. Collectively, these five patents are referred to in this complaint as the "original QVAR patents."

211. The '573 patent, entitled "Medicinal Aerosol formulations," was issued by the PTO on June 16, 1998. It contained one independent claim and two dependent claims.

212. The '573 patent claims a method of *delivering* a drug, not a method of *using* a drug to treat a medical condition.

213. The '573 patent expired November 28, 2009.

214. 3M submitted the '432, '674, '743, and '677 patents as drug product patents (even though two of them did not claim beclomethasone dipropionate). It submitted the '573 patent as a method-of-use patent.

4. Through a product license and a corporate acquisition, Teva became the owner of the QVAR NDA and original QVAR patents.

215. On April 2002, 3M announced that it had granted an exclusive U.S. license, and a non-exclusive worldwide license, to market QVAR to a company called Ivax Corporation ("Ivax"). The license deal gave Ivax the rights to obtain ownership of the U.S. QVAR trademark, as well as related patents and the NDA after five years.

216. 3M reported this change to the FDA in a "changes being effected" notification dated January 31, 2003; and the FDA approved a change to the QVAR label to reflect that Ivax would be QVAR's distributor, effective August 1, 2003.

217. On July 25, 2005, Teva announced that it had acquired Ivax, including its "significant respiratory business" that also included Ivax's QVAR license. Teva and Ivax completed the acquisition in 2006, and Ivax became a subsidiary of Teva.

218. On June 4, 2007, 3M assigned the '432 patent to Ivax LLC. It did not, however, assign the '743, '677, '674, or '573 patents to Ivax.

219. In or around April 2007, Ivax, now a subsidiary of Teva, obtained the trademark and NDA for QVAR from 3M, consistent with the licensing agreement struck in 2002. Teva claimed QVAR as its own product, and the FDA thereafter directed correspondence concerning QVAR to Teva.

5. Neither Teva nor Norton invented metered dose inhalers.

220. Neither Teva nor Norton invented the inhaler, or even the metered-dose inhaler—or even a metered dose inhaler with a dose counter.

221. The invention of the inhaler dates back to the founding of this country. The first inhaler, called the "Mudge Inhaler" was invented in 1778.

222. Nebulizers and dry-powder inhalers were invented in the 1800s.

223. The metered dose inhaler was invented as early as 1956.

6. Neither Teva nor Norton invented the concept of a counter on a metered dose inhaler.

224. The idea to add a dose counter to an inhaler did not originate with Teva or Norton. Nor were those companies the first to add a dose counter to an inhaler.

225. The idea of a dose counter was widely practiced for decades before Teva acquired QVAR. By the early 2000s, many manufacturers of inhaled asthma products contemplated adding dose counters to their rescue inhaler products. Some dose counters operated as a gear, turned one notch each time the aerosol container was pressed into the inhaler, dispensing a dose. Others used a scrolling tape, wound around a roll, and slowly unrolled, dose by dose, revealing the number of remaining doses. Yet others used an electronic dose counter.

226. 3M itself had filed a patent application for an inhaler that indicated the quantity of doses dispensed or remaining in an aerosol vial—using a rotatable indicator—in November 1991, claiming priority to a British application filed a year earlier.

227. But 3M did not include the dose counter on the inhaler that it proposed to use with QVAR when it filed its QVAR NDA.

228. And with good reason.

229. Dose counters can be an important feature of a rescue inhaler—that is, an inhaler taken when a patient is having an asthma attack. Since the frequency, timing, and number of doses a patient may take is dictated not by a typical dosing schedule (i.e., once a day, twice a day, three times a day), a patient must know when their medicine, which is contained within an opaque metal container, is running low. Otherwise, patients risk finding themselves without critical rescue medication in the middle of a life-threatening health emergency.

230. The dose counter's importance and utility does not carry over to maintenance asthma products. If a patient takes a maintenance medication on a predictable schedule, the date on which the inhaler will be empty is knowable and predictable. For example, if an inhaler contains 200 doses of an asthma medication, and a patient uses it twice a day, the patient knows she needs a refill after 100 days.

231. A dose counter is therefore not essential—or particularly useful—to maintenance asthma drug products.

232. But this did not stop Teva from adding a dose-counter to the inhaler sold with QVAR, and leveraging that immaterial change to delay competition.

B. As the original QVAR patents approached expiry, Teva engaged in an overarching anticompetitive scheme.

233. With patent expiry fast approaching, Teva searched for ways to prolong its monopoly over QVAR. What started small, with just one wrongful submission to

the Orange Book, quickly grew into a multifaceted, overarching anticompetitive scheme that stretched for years, and has blocked affordable generic versions of an essential asthma product from the market for almost a decade.

1. January – August 2014: Teva added an unnecessary dose counter invented by Norton to its QVAR product.

234. In 2003, the FDA issued a guidance document, requiring all *new* metered dose inhaler products to have a dose counter or dose indicator. In issuing this guidance, the FDA specifically said that it was not "intended for manufacturers of already marketed MDI drug products."

235. Nevertheless, Teva drew inspiration from this Guidance. It partnered with Norton, which had obtained a patent claiming a dose counter for a metered dose inhaler: U.S. Patent No. 6,446,627 (the '627 patent). And Norton had several more patent applications covering dose counters, or aspects of dose counters, in its pipeline.

236. Teva first obtained ownership of the QVAR NDA and intellectual property in 2007. But it did not seek to add a dose counter to the QVAR metered dose inhaler in 2007. Or in 2008. Or 2009, 2010, 2011, 2012, or 2013.

237. Instead, it waited until 2014. In 2014, Teva knew that the lawful patent monopoly over QVAR—protected by the '432 patent—was set to expire in July 2015. It sought a way to delay competition and prolong its supracompetitive profits beyond the expiration of the '432 patent. But the only way to do that would be to list in the Orange Book another patent, with a later expiration date, that claimed the drug product QVAR.

238. On January 21, 2014—just 18 months before QVAR's patent expiration was due to expire—Teva filed supplemental New Drug Application (or sNDA) 20-911/S-026 to change QVAR. Specifically, it sought approval to add a dose counter to its QVAR product.

239. On May 22, 2014, the FDA approved the sNDA.

240. Once Teva had converted its QVAR product to include an inhaler with a dose counter on it, it sought to make sure that change could hinder competition. On October 21, 2014, it submitted to the FDA a citizen petition, asking the FDA to refuse to approve any generic QVAR product unless "the proposed generic product incorporates a dose counter that functions in the same manner and has the same labeled instructions for use as QVAR®'s dose counter, as demonstrated by appropriate studies."

241. By the point Teva submitted this petition, it already knew what answer the FDA would give. That is because the FDA had issued several draft guidances, and responded to not one, not two, but three other petitions by Teva on the same topic. In 2003, the FDA issued guidance stating it expected all new metered-dose inhaler products to contain a dose counter. In two other guidances addressing specific asthma medications, the FDA had already explained that any generic version of a brand-name drug with a dose counter should also have a dose counter. And when Teva submitted petitions, the FDA responded consistent with those guidances.

242. On May 20, 2015, the FDA responded to Teva's request. It once again told Teva that, for any brand-name medication in a metered-dose inhaler with a dose counter, the FDA intended to require a generic to also have a dose counter.

243. So, although brand-name drug companies acting in good faith do not request the FDA to take an action the agency is already taking, or to adopt a policy that it has already adopted, that is just what Teva did. Teva's 2014 petition is nothing more than an attempt to confirm that it would succeed in its intent to thwart competition through the addition of an unnecessary dose counter to its QVAR product.

2. August 2014 – November 2016: Teva wrongfully lists device-only patents in the Orange Book as claiming the drug product QVAR.

244. On July 7, 2015, when the '432 patent (the latest expiring of the original QVAR patents) expired, Teva's lawful monopoly over QVAR should have ended. But Teva submitted two more patents for listing in the Orange Book. Neither patent claimed the drug product QVAR. These wrongful listings unlawfully prolonged its monopoly until December 18, 2018.

i. Teva wrongfully caused the '627 patent to be listed in the Orange Book as a QVAR drug product patent.

245. In August 2014, Teva submitted a Patent Listing Form, identifying the '627 patent for listing in the Orange Book. On that form, Teva represented in response to Question 3.1 that the '627 patent was a drug product patent, and an employee or agent of Teva certified, on its behalf that "I am familiar with 21 CFR 314.53 and this

submission complies with the requirements of the regulation," and "verif[ied] under penalty of perjury that the foregoing is true and correct."

246. The '627 patent issued September 10, 2002.

247. The '627 patent had a whopping 33 claims in it: 7 independent claims and 26 dependent claims.

248. None of the claims in the '627 patent claims a dose counter in combination with beclomethasone dipropionate. Nor do the words beclomethasone dipropionate appear in the patent's specification.

249. The '627 patent does not mention, let alone claim, beclomethasone dipropionate.

250. The '627 patent was listed in the Orange Book as a drug product patent. That means that Teva identified it as such in the '627 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

251. Because the '627 patent does not mention, let alone claim, beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

252. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '627 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

253. Because Teva wrongfully submitted the '627 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product

QVAR—to be listed in the Orange Book under the entry for QVAR beginning in August 2014.

254. The '627 patent expired December 18, 2017.

ii. Teva wrongfully caused the '289 patent to be listed in the Orange Book as a QVAR drug product patent.

255. In November 2016, Teva submitted a Patent Listing Form for another patent: U.S. Patent No. 9,463,289 (the '289 patent), entitled "Dose counters for inhalers, inhalers and methods of assembly thereof."

256. The PTO issued the '289 patent on October 11, 2016. It contains one independent claim and 9 dependent claims.

257. None of the claims of the '289 patent claims a dose counter in combination with beclomethasone dipropionate. In fact, the words "beclomethasone dipropionate" appear nowhere in the '289 patent.

258. The '289 patent does not mention, let alone claim, beclomethasone dipropionate.

259. The '289 patent was listed in the Orange Book as a drug product patent. That means that Teva identified it as such in the '289 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

260. Because the '289 patent does not mention, let alone claim, beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

261. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '289 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, was also false.

262. Because Teva wrongfully submitted the '289 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

263. The '289 patent, if valid, does not expire until May 18, 2031.

3. October 2016 - February 2018: Teva executed a hard-switch product hop to prevent competition.

264. On October 3, 2016, Norton submitted, through Teva, NDA 20-7921, a § 505(b)(2) application, seeking approval to make, market, and sell a "new" product.

265. That product, Norton proposed, would be called the QVAR Redihaler, which is just QVAR's active ingredient in a new, proprietary inhaler device. Whereas a typical inhaler dispenses medication when the medication cannister is depressed into the inhaler device, the Redihaler is "breath actuated," meaning it dispenses medication when the user breathes in.

266. The FDA characterized Norton's proposed QVAR Redihaler as "a breath-actuated version of the applicant's QVAR Inhalation Aerosol." It characterized the drug substance of QVAR as beclomethasone dipropionate—the same as QVAR. And it characterized the drug product as a "solution formulation."

267. On August 3, 2017, the FDA approved Norton's QVAR Redihaler application, clearing the way for Teva to launch QVAR Redihaler.

268. Teva's press release touting the approval announced the product hop:

> QVAR® MDI with dose counter, the currently available form of QVAR®, was originally approved by the FDA in 2014. Teva plans to discontinue sales of this current QVAR® MDI formulation upon the launch of QVAR® Redihaler™ in the first quarter of 2018.

269. On February 16, 2018, Teva launched QVAR Redihaler. When it announced the launch, Teva also announced it was "discontinuing sales of the previously available QVAR®."

270. Teva priced QVAR Redihaler "at parity to QVAR®."

4. August 2017 - present: Teva improperly listed a slew of patents in the Orange Book to block competition to QVAR Redihaler.

271. The '432 patent expired three years before Teva obtained approval for QVAR Redihaler, so Teva was not able to submit that patent for listing in the Orange Book under the entry for QVAR Redihaler.

272. Instead, Teva listed thirteen other patents in the Orange Book as claiming QVAR Redihaler—four when the FDA approved QVAR Redihaler, and another eight over the next five years. A table of Teva's QVAR Redihaler submissions is attached as Appendix A.

273. All of the patents claimed an inhaler device, or just a portion of an inhaler device. Only two patents—which did not issue and were not listed until years after QVAR Redihaler's approval—include beclomethasone dipropionate as a product claim element and arguably could be listed as a drug product patent for QVAR Redihaler.

274. None of the other patents that Teva caused to be listed in the Orange Book claimed the drug product QVAR Redihaler.

275. But that did not stop Teva from larding up their QVAR Redihaler Orange Book entry with patents that should not have been listed.

276. Upon approval in August 2017, Teva submitted four patents to the Orange Book.

i. Teva wrongfully caused the '627 patent to be listed in the Orange Book as a QVAR Redihaler drug product patent.

277. First, Teva submitted the '627 patent—the same patent it had submitted in 2014 as claiming QVAR—as a drug product patent. As noted above, the '627 patent did not mention, let alone claim, beclomethasone dipropionate. As a result, and for the reasons described above, the information provided in Teva's Patent Listing Form was false, yet a representative of the companies falsely certified, under penalties of perjury, that the information was accurate.

ii. Teva wrongfully caused the '260 patent to be listed in the Orange Book as a QVAR Redihaler drug product patent.

278. Second, Teva submitted a Patent Listing Form for U.S. Patent No. 7,637,260 (the '260 patent), entitled "Medicament dispensing device with a multimaterial diaphragm bounding a pneumatic force chamber."

279. The '260 patent issued on December 29, 2009, and contains 12 claims: 2 independent claims and 10 dependent claims.

280. None of those claims combine the inhaler device with beclomethasone dipropionate. In fact, the words "beclomethasone dipropionate" do not appear anywhere in the '260 patent.

281. The ’260 patent does not claim, let alone mention beclomethasone dipropionate.

282. Teva submitted the ’260 patent as a drug product patent. That means that Teva identified it as such in the ’260 patent Patent Listing Form by answering “yes” to Question 3.1—whether the patent “claim[s] the approved drug product *as defined in 21 CFR 314.3*.”

283. Because the ’260 patent does not mention, let alone claim, beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva’s response to Question 3.1 was false.

284. Because Teva’s answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the ’260 patent Patent Listing Form “complies with the requirements of” 21 C.F.R. § 314.53, is also false.

285. Because Teva wrongfully submitted the ’260 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

286. The ’260 patent, if valid, expired November 2, 2022.

iii. Teva wrongfully caused the ’712 patent to be listed in the Orange Book as a QVAR Redihaler drug product patent.

287. Third, Teva submitted U.S. Patent No. 8,132,712 (the ’712 patent), entitled “Metered-dose inhaler.”

288. The ’712 patent issued on March 13, 2012, and contains 19 claims: 3 independent claims and 16 dependent claims. None of the ’712 patent’s claims combine an inhaler with beclomethasone dipropionate.

289. The phrase "beclomethasone dipropionate" appears only in the patent's specification. Accordingly, the '712 patent does not claim either the drug substance beclomethasone dipropionate or a drug product "that contains" beclomethasone dipropionate.

290. Teva submitted the '712 patent as a drug product patent. That means that Teva identified it as such in the '712 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

291. Because the '712 patent does not claim beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

292. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '712 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

293. Because Teva wrongfully submitted the '712 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

294. The '712 patent, if valid, does not expire until September 7, 2028.

iv. Teva wrongfully caused the '476 patent to be listed in the Orange Book as a QVAR Redihaler drug product patent.

295. Fourth, Teva submitted U.S. Patent No. 8,931,476 (the '476 patent), entitled "Inhaler."

296. The '476 patent issued on January 13, 2015, and contains 18 claims—2 independent claims and 16 dependent claims.

297. Independent claim 1 of the '476 patent reads:

> An inhaler for delivering medicament to a patient, the inhaler comprising a housing for holding the medicament and having an air inlet means and a medicament delivery port which together define an air flow path into which the medicament is dispensed,
>
> wherein the air inlet means comprises an array of elongate apertures formed in the housing, wherein long sides of adjacent apertures face each other, and each aperture being provided with a respective different opening in an outer surface of the housing,
>
> and wherein the opening of each aperture extends in two different planes such that, if at least a part of the opening is covered in one of two different planes during inhalation by the patient, a void space is created between a cover and the aperture so as to provide an air flow path through the void space to the at least one aperture, wherein a raised formation is provided in the outer surface of the housing between adjacent apertures to either limit or prevent a covered opening.

298. Dependent claim 15 reads:

> An inhaler according to claim 1, wherein the medicament is selected from the group consisting of salbutamol, formoterol, salmeterol, fluticasone, budesonide, *beclomethasone*, tiotropium, ipratropium and combinations thereof.

299. Dependent claim 15 does *not* claim beclomethasone dipropionate. It claims only beclomethasone—which lacks the diester group that characterizes beclomethasone dipropionate.

300. None of the claims of the '476 patent recite beclomethasone dipropionate.

301. The '476 patent does not claim either the drug substance beclomethasone dipropionate or a drug product "that contains" beclomethasone dipropionate.

302. Teva submitted the '476 patent as a drug product patent. That means that Teva identified it as such in the '476 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

303. Because the '476 patent does not claim beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

304. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '476 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

305. Because Teva wrongfully submitted the '476 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

306. The '476 patent, if valid, does not expire until July 17, 2031.

v. Teva wrongfully caused the '509 patent to be listed in the Orange Book as a QVAR Redihaler drug product patent.

307. Even after Teva listed these four device-only, non-drug-product patents to the Orange Book, it continued to list patents that did not claim the QVAR drug substance or drug product in the Orange Book.

308. In July 2018, Teva submitted a Patent Listing Form to the FDA for U.S. Patent No. 10,022,509 (the '509 patent), entitled "Dose counter for inhaler having a bore and shaft arrangement."

309. The '509 patent issued on July 17, 2018, and contains 16 claims: 1 independent claim and 15 dependent claims.

310. None of the '509 patent's claims recite beclomethasone dipropionate. In fact, the words "beclomethasone dipropionate" do not appear anywhere in the patent.

311. The '509 patent does not mention, let alone claim, beclomethasone dipropionate.

312. Teva submitted the '509 patent as a drug product patent. That means that Teva identified it as such in the '509 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

313. Because the '509 patent does not mention, let alone claim, beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

314. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '509 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

315. Because Teva wrongfully submitted the '509 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

316. The '509 patent, if valid, does not expire until May 18, 2031.

vi. Teva wrongfully caused the '510 patent to be listed in the Orange Book as a QVAR Redihaler drug product patent.

317. In July 2018, Teva also submitted a Patent Listing Form for U.S. Patent No. 10,022,510 (the '510 patent), entitled "Dose counters for inhalers, inhalers and methods of assembly thereof."

318. The '510 patent was issued on July 17, 2018, and has 23 claims: 3 independent claims and 20 dependent claims.

319. None of the '510 patent's claims recite beclomethasone dipropionate. In fact, the words "beclomethasone dipropionate" do not appear anywhere in the patent.

320. The '510 patent does not mention, let alone claim, beclomethasone dipropionate.

321. Teva submitted the '510 patent as a drug product patent. That means that Teva identified it as such in the '510 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

322. Because the '510 patent does not mention, let alone claim, beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

323. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '510 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

324. Because Teva wrongfully submitted the '510 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

325. The '510 patent, if valid, does not expire until May 18, 2031.

vii. Teva wrongfully caused the '156 patent to be listed in the Orange Book as a QVAR Redihaler drug product patent.

326. In October 2018, Teva submitted a Patent Listing Form for U.S. Patent No. 10,086,156 (the '156 patent), entitled "Dose counter for inhaler and method for counting doses."

327. The '156 patent was issued on October 2, 2018, and contains 13 claims: 1 independent claim and 12 dependent claims.

328. None of the '156 patent's claims recite beclomethasone dipropionate. In fact, the words "beclomethasone dipropionate" do not appear anywhere in the patent.

329. The '156 patent does not mention, let alone claim, beclomethasone dipropionate.

330. Teva submitted the '156 patent as a drug product patent. That means that Teva identified it as such in the '156 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

331. Because the '156 patent does not mention, let alone claim, beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

332. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '156 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

333. Because Teva wrongfully submitted the '156 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

334. The '156 patent, if valid, does not expire until May 18, 2031.

viii. Teva wrongfully caused the '512 patent to be listed in the Orange Book as a QVAR Redihaler drug product patent.

335. In July 2020, Teva submitted a Patent Listing Form for U.S. Patent No. 10,695,512 (the '512 patent), entitled "Dose counter for inhaler having an anti-reverse rotation actuator."

336. The '512 patent issued on June 30, 2020, and has 6 claims: 1 independent claim and 5 dependent claims.

337. None of the '512 patent's claims recite beclomethasone dipropionate. In fact, the words "beclomethasone dipropionate" do not appear anywhere in the patent.

338. The '512 patent does not mention, let alone claim, beclomethasone dipropionate.

339. Teva submitted the '512 patent as a drug product patent. That means that Teva identified it as such in the '512 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

340. Because the '512 patent does not mention, let alone claim, beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

341. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '512 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

342. Because Teva wrongfully submitted the '512 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

343. The '512 patent, if valid, does not expire until Mar. 15, 2032.

ix. Teva wrongfully caused the '808 patent to be listed in the Orange Book as a QVAR Redihaler drug product patent.

344. In March 2020, Teva submitted a Patent Listing Form for U.S. Patent No. 10,561,808, entitled "Dose counter for inhaler having an anti-reverse rotation actuator."

345. The '808 patent issued on February 18, 2020, and contains 29 claims: 1 independent claim and 28 dependent claims.

346. None of the '808 patent's claims recite beclomethasone dipropionate. In fact, the words "beclomethasone dipropionate" do not appear anywhere in the patent.

347. The '808 patent does not mention, let alone claim, beclomethasone dipropionate.

348. Teva submitted the '808 patent as a drug product patent. That means that Teva identified it as such in the '808 patent Patent Listing Form by answering

"yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

349. Because the '808 patent does not mention, let alone claim, beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

350. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '808 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

351. Because Teva wrongfully submitted the '808 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

352. The '808 patent, if valid, does not expire until December 22, 2031.

x. After years of obtaining patents and improperly listing them in the Orange Book Teva may have finally gotten one right.

353. In October 2020, Teva submitted a Patent Listing Form for U.S. Patent No. 10,792,447 (the '447 patent), entitled "Breath actuated inhaler."

354. The '447 patent issued on October 6, 2020, and contains 10 claims: 2 independent and 8 dependent claims.

355. Independent claim 1 of the patent reads:

> A breath actuated metered dose inhaler comprising:
>
> > a canister fire system configured to provide a canister actuation force to fire a medicament containing canister in response to patient inhalation, the canister fire system comprising a pneumatic force holding unit and having:

> a rest configuration in which a metering valve of the canister is in a refill configuration;
>
> a prepared configuration in which a canister actuation force is retained by a difference in pressure between an enclosed volume within the pneumatic force holding unit and atmospheric pressure, and in which prepared configuration the canister fire system is actuatable by patient inhalation induced airflow;
>
> and a fire configuration in which the metering valve is in a dose delivery position;
>
> wherein, in the prepared configuration, the force retained by the pneumatic force holding unit reduces but by less than about 6% over a period of 5 minutes.

356. Dependent claims 4 through 6 read:

> 4. The breath actuated metered dose inhaler according to claim 1 comprising a medicament for use in the treatment of a respiratory disease.
>
> 5. The breath actuated inhaler according to claim 4 wherein the respiratory disease is selected from COPD and asthma.
>
> 6. The breath actuated inhaler according to claim 5 wherein the medicament is selected from the group consisting of an anticholinergic and a corticosteroid.

357. And dependent claim 8 reads:

> 8. The breath actuated inhaler according to claim 6, wherein the corticosteroid comprises beclomethasone dipropionate.

358. Thus, claim 8 claims a breath actuated inhaler (claim 1) containing a medicament for use in the treatment of a respiratory disease (claim 4); where the respiratory disease is either COPD or asthma (claim 5) and the medicament contains beclomethasone dipropionate (claims 6 and 8).

359. No other claim of the '447 patent recites beclomethasone dipropionate. Therefore, based on claim 8 of the '447 patent, the '447 patent, in theory, could have been listed for the QVAR Redihaler drug product if the other mechanical claim limitations incorporated in claim 8 were also present in the approved QVAR Redihaler. However, the priority filing date for the '447 patent is subsequent to the NDA approval date of the QVAR Redihaler. This strongly suggests that the '447 patent is facially invalid as the QVAR Redihaler product that was approved by the FDA predates the priority date of the '447 patent and, thus, should be invalidating prior art.

360. The '447 patent, if valid, does not expire until January 25, 2039.

361. Teva did not list the '447 patent for more than three years after QVAR Redihaler's approval. It therefore could not have blocked competition from any would-be competitor who filed an ANDA between 2017 and mid-2020. Had Teva *not* improperly listed all of the other patents described herein, there would have been *no* patents listed in the Orange Book as claiming QVAR for three years, and a would-be competitor would have been incentivized to submit an application for a competing product. But because Teva larded up the Orange Book with improper listings of patents that did not claim the drug product QVAR Redihaler, it was able to create a daunting wall of patents to which would-be competitors would be forced to make paragraph IV certifications. That wall of patents served as a deterrent to competition.

xi. Teva wrongfully caused the '889 patent to be listed in the Orange Book as a QVAR Redihaler drug product patent.

362. In August 2022, Teva submitted a Patent Listing Form for U.S. Patent No. 11,395,889 (the '889 patent), entitled "Dose counter for inhaler having an anti-reverse rotation actuator."

363. The '889 patent issued on July 26, 2022, and contains 6 claims: 1 independent claim and 5 dependent claims.

364. None of the '889 patent's claims recite beclomethasone dipropionate. In fact, the words "beclomethasone dipropionate" do not appear anywhere in the patent.

365. The '889 patent does not mention, let alone claim, beclomethasone dipropionate.

366. Teva submitted the '889 patent as a drug product patent. That means that Teva identified it as such in the '889 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

367. Because the '889 patent does not mention, let alone claim, beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

368. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '889 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

369. Because Teva wrongfully submitted the '889 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

370. The '889 patent, if valid, does not expire until May 18, 2031.

xii. Teva caused the '888 patent to be listed in the Orange Book as claiming QVAR Redihaler.

371. In August 2022, Teva submitted a Patent Listing form for U.S. Patent No. 11,395,888 (the '888), entitled "Inhalers and Related Methods."

372. The '888 patent issued on July 26, 2022, and contains 30 claims: 2 independent claims and 28 dependent claims.

373. Claim 1 describes a breath-actuated inhaler. Independent claim 10 describes that breath-actuated inhaler containing beclomethasone dipropionate.

374. Assuming that the Redihaler device includes all of the other claim elements of claim 1 of the '888 patent this claim could in theory be listed for the drug product QVAR Redihaler.

375. The '888 patent issued from U.S. Patent Application No. 16/134,401, which was a continuation of U.S. Patent Application No. 15/881,283, which was originally filed in January 2018. The original '283 application did not include any proposed claim that described the Redihaler device in combination with beclomethasone dipropionate. Teva specifically filed the '401 continuation application to add claims which claimed the QVAR Redihaler drug product.

376. This and claim 8 of the '447 patent demonstrate that Teva knew how to—and knew it should—obtain a patent that claimed the drug product QVAR

Redihaler in combination with the inhaler device to properly list a patent for a QVAR drug product in the Orange Book. Yet it did not even attempt to obtain such patents until *after* QVAR Redihaler was approved, and in the meantime improperly listed patents for the QVAR Redihaler.

377. But that, alone, was not enough to allow Teva to block all competition to its QVAR franchise. A would-be competitor may be able to design around one or two patents; and that would-be competitor would have greater incentives to do so when only one or two patents stood in its way, as opposed to a dozen patents.

xiii. Teva resumed listing improper patents, wrongfully causing the '637 and '643 patent to be listed in the Orange Book as a QVAR Redihaler drug product patent.

378. In February 2023, Teva submitted a Patent Listing Form for U.S. Patent No. 11,559,637 (the '637 patent), entitled "Inhalers and related methods."

379. The '637 patent issued on January 24, 2023, and contains 50 claims: 2 independent and 48 dependent claims.

380. Claim 1 of the '637 patent reads:

> A breath actuated inhaler comprising:
>
> a main body for accommodating a medicament reservoir;
>
> a cannister firing system including
>
> a trigger; and
>
> a biasing element for moving a cannister to release a dose in response to air flow,
>
> a cap housing,

> an interior chamber defined by the main body and the cap housing, the cannister fire system and canister being enclosed within the interior chamber, and
>
> a lock system including helical threads having non-overlapping and distinct thread segments for providing rotational attachment of the cap housing to the main body and a first lock member that cooperated with a second lock member to achieve a snap lock between the cap housing and the main body when the cap housing is rotationally attached to the main body in a locked position,
>
> wherein the thread segments are radially disposed about a central axis and arranged such that the thread segments are non-overlapping with respect to each other along the central axis, and
>
> wherein the first lock member is interposed between the thread segments.

381. Dependent claim 11 reads: "A method of treating a respiratory disease or disorder comprising actuating the inhaler of claim 1 to administer a therapeutically effective amount of one or more active ingredients."

382. And claim 16 reads: "The method of claim 11, wherein the one or more active ingredients comprise beclomethasone dipropionate or tiotropium bromide."

383. Independent claim 28 reads:

> A breath actuated inhaler comprising: a main body for accommodating a medicament reservoir, a canister fire system for moving a canister to release a dose in response to air flow, a cap housing for enclosing the canister fire system and canister within an interior chamber defined by the main body and the cap housing, and in which the main body and the cap housing are formed of plastics material characterized in that a lock system is provided for locking the cap housing on the main body,
>
> wherein the lock system includes:

> helical threads having non-overlapping and distinct thread segments for providing rotational attachment of the cap housing on the main body; and
>
> a first lock member that cooperates with a second lock member to achieve a snap lock between the cap housing and the main body when the cap housing is rotationally attached to the main body in a locked position,
>
> wherein the thread segments are radially disposed about a central axis and arranged such that the thread segments are non-overlapping with respect to each other along the central axis, wherein the first lock member is interposed between the thread segments, and
>
> wherein a release torque required to overcome the lock system is more than 1 Nm and lower than 4 Nm.

384. Dependent claim 34 reads: "A method of treating a respiratory disease or disorder comprising actuating the inhaler of claim 28 to administer a therapeutically effective amount of one or more active ingredients."

385. And dependent claim 39 reads: "The method of claim 34, wherein the one or more active ingredients comprise beclomethasone dipropionate or tiotropium bromide."

386. Neither independent claim 1 nor independent claim 28 of the '637 patent claims the drug product QVAR Redihaler. Neither claims an inhaler device in combination with beclomethasone dipropionate.

387. Dependent claims 16 and 39 mention beclomethasone dipropionate, but both claim a method of using an inhaler containing QVAR Redihaler's drug substance; they do not claim the drug substance or a drug product containing a drug substance.

388. Yet in February 2023, Teva submitted the '637 patent for listing in the Orange Book as a drug product patent. That means that Teva identified it as such in the '637 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

389. Because the '637 patent does not claim an inhaler in combination with beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

390. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '637 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

391. Because Teva wrongfully submitted the '637 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

392. The '637 patent, if valid, does not expire until July 21, 2039.

393. In March 2023, Teva submitted a Patent Listing Form for U.S. Patent No. 11,583,643 (the '643 patent), entitled "Inhalers and related methods."

394. The '643 patent issued on February 21, 2023, and contains 40 claims: 1 independent claim and 39 dependent claims.

395. Claim 1 of the '643 patent reads:

> A method of metering inhalable substances, the method comprising:
>
> > providing a medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a

> communication path between the metering chamber and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir;
>
> operating the medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber;
>
> following the time period, orienting the interior reservoir above the metering chamber to permit the atmospheric air within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and
>
> administering, from the liquid replacement, 75% to 125% of labelled claim for a dose.

396. Dependent claim 16 claims "[a] method of treating a respiratory disease or disorder to administer a therapeutically effective amount of one or more active ingredients, the method including carrying out the method of claim 1."

397. And dependent claim 21 claims "The method of claim 16, wherein the one or more active ingredients comprise beclomethasone dipropionate or tiotropium bromide."

398. Norton filed the PTO application leading to the '643 patent in January 2018. In the original application, Norton purported to claim (1) the method of using an inhaler that ultimately appeared in the '643 patent, (2) an inhaler device, and (3) a method of using a metering valve.

399. Norton's proposed inhaler claims appeared in proposed claims numbered 18-50. Proposed claim 18 purported to claim:

> An inhaler for the inhalation of inhalable substances, the inhaler comprising: a canister having an interior reservoir containing pressurized inhalable substances including fluid; a metering valve including a metering chamber and a valve stem defining a communication path between the metering chamber and a valve stem defining a communication path between the metering chamber and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir, the interior reservoir being arranged for orientation above the metering chamber whereby gas such as air located within the metering chamber is replaced with liquid from the interior reservoir.

And in proposed claim 37, Norton purported to claim "[t]he inhaler of Claim 18 which includes at least one inhalable substance in the interior reservoir as an active ingredient, for example in suspension or in solution, such as beclomethasone dipropionate or tiotropium bromide."

400. If the '643 patent had issued with the claims contained within the original proposed claims 18-50, it may have been properly listable in the Orange Book as a drug product patent because proposed claim 37 claimed a device ("[t]he inhaler of Claim 18") in combination with QVAR's active ingredient, beclomethasone dipropionate.

401. But in February 2021, the PTO's patent examiner told Norton it had to choose: it could claim *either* the claims "drawn to methods of metering and treating" that appeared in the original proposed claims as Claims 1-17 and 55-61 *or* "Claims 18-50, drawn to an inhaler," *or* claims "drawn to the use of a metering valve." It could not claim all three of these categories; and it could not choose two.

402. In July 2021, Norton chose to pursue the claims drawn to methods of metering and treating. It canceled all claims in the '643 patent's application that claimed an inhaler. In other words, Norton gave up the opportunity to claim, in the application that became the '643 patent, a device in combination with the active ingredient of QVAR.

403. Each and every one of the relevant claims in the '643 patent, as issued, claims "*a method*"—not a drug product. And Teva and Norton knew that: they expressly chose to pursue method claims, rather than drug product claims, for this patent. Instead, it obtained a patent that, arguably, claimed a method of using QVAR.[4]

404. Teva submitted the '643 patent to the FDA for listing in the Orange Book as a drug product patent. That means that Teva identified it as such in the '643 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*." Because the '643 patent does not claim an inhaler in combination with beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

405. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '643 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

[4] This allegation is not intended to suggest, imply, or raise the inference that the '643 was valid; in fact, it is likely *in*valid as obvious over prior art, since both the inhaler described in the method-of-use patent and the drug used had been commercialized more than one year prior to the application's priority date.

406. Because Teva wrongfully submitted the '643 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

407. The '643 patent, if valid, does not expire until August 19, 2041.

408. These false statements—that the '637 and '643 patents claim a drug product, rather than a method of use—are consequential. Because Teva submitted the '637 and '643 patents along with sworn statements that it was a drug product patent, and not a method-of-use patent, would-be generic competitors would be forced to submit a paragraph IV certification, and not a section viii carveout, if they sought to market a generic product prior to patent expiry. This (wrongfully) ensures that Teva has an opportunity to file a patent infringement suit (and, if it has no reasonable basis to do so, a sham patent infringement suit) against a would-be competitor, automatically delaying approval of that competitor's ANDA for two and a half years.

5. Despite Teva's hard-switch product hop and the thicket of wrongful patent listings it constructed around QVAR Redihaler, it still faced the risk of generic competition.

409. Teva did not discontinue QVAR for any safety or effectiveness reason. Rather, "Teva made a business decision to discontinue manufacturing" QVAR.

410. In September 2018, Aurolife Pharma LLC, a subsidiary of Aurobindo Pharma USA, submitted a citizen petition to the FDA, asking whether Teva withdrew QVAR for safety or effectiveness reasons. In April 2019, the FDA answered "no."

411. Because the FDA determined that Teva's decision to withdraw QVAR from the market had nothing to do with safety or effectiveness, it decided that QVAR would remain listed in the "Discontinued Drug Product List" in Orange Book, and

that the agency would review and "approve abbreviated new drug applications (ANDAs) for QVAR . . . (beclomethasone dipropionate HFA) inhalation aerosol . . . if all other legal and regulatory requirements are met."

412. This was good news for would-be competitors who had already begun the process of creating generic versions of QVAR. It was good news for patients, who could look forward to affordable generic versions of their asthma medication. And it was good news for entities that paid for QVAR prescriptions, who could look forward to substantial cost-savings when generic QVAR launched.

413. But it was bad news for Teva: it meant that would-be generic competitors could obtain approval for generic QVAR, and that it could be automatically substituted for prescriptions written for just "QVAR," instead of "QVAR Redihaler." Teva's efforts to prevent competition were at risk.

6. November 2018 – present: Teva prevented generic QVAR competition by listing an additional 7 device-only patents in the Orange Book as QVAR drug product patents.

414. Teva knew that, so long as generic versions of QVAR could be approved by reference to its QVAR product, its stranglehold over the market for the QVAR franchise, and its already-two-years-prolonged monopoly were at risk.

415. Beginning in November 2017—after Teva had already announced they would discontinue QVAR—the companies submitted another seven patents for listing in the Orange Book as QVAR drug product patents, blockading competition to a drug they no longer sold. A table of Teva's QVAR submissions is attached as Appendix B.

i. Teva wrongfully caused the '587 patent to be listed in the Orange Book as a QVAR drug product patent.

416. In November 2017, Teva submitted a Patent Listing Form for U.S. Patent No. 9,808,587 (the '587 patent), entitled "Dose Counter for inhaler having an anti-reverse rotation actuator."

417. The '587 patent issued November 7, 2017, and contained 22 claims: 3 independent claims and 19 dependent claims.

418. None of the '587 patent's claims recite beclomethasone dipropionate. In fact, the words "beclomethasone dipropionate" do not appear anywhere in the patent.

419. The '587 patent does not mention, let alone claim, beclomethasone dipropionate.

420. Teva submitted the '587 patent as a drug product patent. That means that Teva identified it as such in the '587 patent Patent Listing Form by answering "yes" to Question 3.1—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*."

421. Because the '587 patent does not mention, let alone claim, beclomethasone dipropionate, it does not claim the drug product QVAR. Therefore, Teva's response to Question 3.1 was false.

422. Because Teva's answer to Question 3.1 was false, the certification, *made under penalty of perjury*, that the information in the '587 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53, is also false.

423. Because Teva wrongfully submitted the '587 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR Redihaler.

424. The '587 patent does not expire until May 18, 2031.

ii. Teva wrongfully caused the '509 patent to be listed in the Orange Book as a QVAR drug product patent.

425. In July 2018, Teva submitted a Patent Listing Form for the '509 patent, resulting in the '509 patent being listed in the Orange Book under QVAR.

426. Teva submitted this patent listing form at or around the time that it submitted the '509 patent Patent Listing form for QVAR Redihaler.

427. As noted above, the '509 patent does not claim, let alone mention beclomethasone dipropionate.[5]

428. Therefore, for the reasons described above, Teva's answer to Question 3.1 on the Patent Listing Form—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*"—was false. So too was the declaration signed by a Teva representative, swearing under penalty of perjury that the information in the '509 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53.

429. Because Teva wrongfully submitted the '509 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product

[5] *See supra* § V.B.4.v.

QVAR—to be listed in the Orange Book under the entry for QVAR, where it will likely remain until the patent expires in 2031.

iii. Teva wrongfully caused the '510 patent to be listed in the Orange Book as a QVAR drug product patent.

430. In July 2018, Teva submitted a Patent Listing Form for the '510 patent, resulting in the '510 patent being listed in the Orange Book under QVAR.

431. Teva submitted this patent listing form at or around the time that it submitted the '510 patent Patent Listing form for QVAR Redihaler.

432. As noted above, the '510 patent does not claim, let alone mention beclomethasone dipropionate.[6]

433. Therefore, for the reasons described above, Teva's answer to Question 3.1 on the Patent Listing Form—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*"—was false. So too was the declaration signed by a Teva or Norton representative, swearing under penalty of perjury that the information in the '510 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53.

434. Because Teva wrongfully submitted the '510 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR, where it will likely remain until the patent expires in 2031.

[6] *See supra* § V.B.4.vi.

iv. Teva wrongfully caused the '156 patent to be listed in the Orange Book as a QVAR drug product patent.

435. In October 2018, Teva submitted a Patent Listing Form for the '156 patent, resulting in the patent being listed in the Orange Book as a QVAR drug product patent.

436. Teva made this submission at or around the same time it submitted the patent for listing under QVAR Redihaler.

437. As noted above, the '156 patent does not claim, let alone mention beclomethasone dipropionate.[7]

438. Therefore, for the reasons described above, Teva's answer to Question 3.1 on the Patent Listing Form—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*"—was false. So too was the declaration signed by a Teva or Norton representative, swearing under penalty of perjury that the information in the '156 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53.

439. Because Teva wrongfully submitted the '156 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR, where it will likely remain until the patent expires in 2031.

[7] *See supra* § V.B.4.vii.

v. Teva wrongfully caused the '512 patent to be listed in the Orange Book as a QVAR drug product patent.

440. In July 2020, Teva submitted a Patent Listing Form for the '512 patent, resulting in the patent being listed in the Orange Book as a QVAR drug product patent.

441. Teva made this submission at or around the same time it submitted the patent for listing under QVAR Redihaler.

442. As noted above, the '512 patent does not claim, let alone mention beclomethasone dipropionate.[8]

443. Therefore, for the reasons described above, Teva and Norton's answer to Question 3.1 on the Patent Listing Form—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*"—was false. So too was the declaration signed by a Teva or Norton representative, swearing under penalty of perjury that the information in the '512 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53.

444. Because Teva wrongfully submitted the '512 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR, where it will likely remain until the patent expires in 2031.

[8] *See supra* § V.B.4.viii.

vi. Teva wrongfully caused the '808 patent to be listed in the Orange Book as a QVAR drug product patent.

445. In March 2020, Teva submitted a Patent Listing Form for the '808 patent, resulting in the patent being listed in the Orange Book as a QVAR drug product patent.

446. Teva made this submission at or around the same time it submitted the patent for listing under QVAR Redihaler.

447. As noted above, the '808 patent does not claim, let alone mention beclomethasone dipropionate.[9]

448. Therefore, for the reasons described above, Teva's answer to Question 3.1 on the Patent Listing Form—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*"—was false. So too was the declaration signed by a Teva or Norton representative, swearing under penalty of perjury that the information in the '808 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53.

449. Because Teva wrongfully submitted the '808 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR, where it will likely remain until the patent expires in 2031.

[9] *See supra* § V.B.4.ix.

vii. Teva wrongfully caused the '889 patent to be listed in the Orange Book as a QVAR drug product patent.

450. In August 2020—five years after Teva announced they would be discontinuing QVAR sales and four and a half years after they did so—they submitted a Patent Listing Form for the '889 patent, resulting in the patent being listed in the Orange Book as a QVAR drug product patent.

451. Teva made this submission at or around the same time it submitted the patent for listing under QVAR Redihaler.

452. As noted above, the '889 patent does not claim, let alone mention beclomethasone dipropionate.[10]

453. Therefore, for the reasons described above, Teva's answer to Question 3.1 on the Patent Listing Form—whether the patent "claim[s] the approved drug product *as defined in 21 CFR 314.3*"—was false. So too was the declaration signed by a Teva or Norton representative, swearing under penalty of perjury that the information in the '889 patent Patent Listing Form "complies with the requirements of" 21 C.F.R. § 314.53.

454. Because Teva wrongfully submitted the '889 patent to the FDA, it wrongfully caused that patent—a patent that does not claim the drug product QVAR—to be listed in the Orange Book under the entry for QVAR, where it will likely remain until the patent expires in 2031.

[10] *See supra* § V.B.4.xi.

7. January 2020: a generic company filed an ANDA, seeking approval to sell an affordable generic version of QVAR—but Teva does not sue.

455. On January 10, 2020, a generic company filed the first ANDA seeking to make, market, and sell an affordable generic version of QVAR.

456. That company was Amneal Pharmaceuticals, Inc.

457. Amneal filed a paragraph IV certification to each of the four device-only patents Teva had wrongfully listed in the Orange Book as claiming QVAR.

458. Teva did not sue Amneal. Because Teva did not sue Amneal within 45 days of receiving the first-filers' ANDA, they were not able to take advantage of the two-and-a-half year stay of FDA approval.

459. Because Teva did not sue, Amneal told investors that they expected to launch its generic QVAR product in 2021. It repeated that statement in each earnings call for the second and third quarters of 2021.

460. Amneal also assured investors that it was not experiencing any problems in the approval process at the FDA that could alter its projected launch timeline.

461. Amneal promised investors, during its third quarter 2020 investors' call, that "as [it] get[s] closer" to its anticipated launch date for generic QVAR, it "will be able to provide more details." In the fourth quarter of 2020, though, Amneal started hedging on its representations about a launch, suggesting it may not occur until 2025, and then fell silent about it after that.

8. February 2020: Teva defies the Orange-Book listing rule announced by the First Circuit.

462. On February 13, 2020, the United States Court of Appeals for the First Circuit issued an opinion in *In re Lantus Direct Purchaser Antitrust Litigation*. The First Circuit explained that "[t]he statute and applicable regulations call for the listing of only patents that claim the pertinent drug or a method of using the drug . . . ." And the court held that it is "readily apparent" that a patent that does not claim a drug's active ingredient or any method of using it, may not legally be listed in the Orange Book.

463. The First Circuit told brand-name drugmakers that they could face antitrust liability for listing and asserting patents that did not satisfy the statutory listing requirements. It dismissed the concern from the *Lantus* defendant, Sanofi, that it could face antitrust liability if it failed to list a patent it was required to list, explaining:

> a company unsure about whether it must submit a patent for listing might protect itself from liability by submitting the patent and then not suing within forty-five days of any subsequent Paragraph IV certification, thereby ensuring that the mere listing would not slow down final FDA approval of a competitor's submission.

464. An NDA holder, like Teva, has an ongoing obligation to amend or correct patent listings. Pursuant to the FDA's regulations implementing the statutory listing requirements:

> If the NDA holder determines that a patent or patent claim no longer meets the requirements for listing in section 505(b)(1) or (c)(2) of the Federal Food, Drug, and Cosmetic Act . . . , the NDA holder is *required* to *promptly* notify FDA to amend the patent information or withdraw the patent or

> patent information and request that the patent or patent information be removed from the list.

465. Where an NDA holder is specifically "required by court order to amend patent information or withdraw a patent from the list, it must submit an amendment to its NDA . . . within 14 days of the date the order was entered . . . ." In any event, though, a brand-name drugmaker is obligated to "promptly" remove a patent from the Orange Book once it knows or has reason to know that its listing is improper.

466. The *Lantus* court recognized that, in some circumstances, a brand-name drugmaker may have a defense to antitrust liability for improper Orange Book listings if it "had a reasonable basis in regulatory policy to conclude, and in good faith concluded," that listing patents that claimed only a device and not a device in combination with a drug product as defined by the federal drug laws and regulations "was necessitated by concrete factual imperatives recognized as legitimate by" the FDA.

467. At least as of February 13, 2020, Teva knew or should have known that any QVAR- or QVAR Redihaler-listed patents that did not claim the active ingredient beclomethasone dipropionate were improperly listed. It was therefore obligated to promptly withdraw all patents that did not contain, within their claims, beclomethasone dipropionate. And after February 13, 2020, Teva could no longer protect its improper listings—or its failure to remove patents already improperly listed—by claiming refuge in the defense announced in the *Lantus* decision.

468. Had Teva complied with the law and/or heeded *Lantus*'s warning, it would have done the following:

- Requested that the FDA withdraw from the Orange Book the listings under QVAR Redihaler of the '260, '712, '476, '509, '510, and '156 patents;
- Requested that the FDA withdraw from the Orange Book the listings under QVAR of the '289, '587, '509, '510, and '156 patents;
- Refrained from listing in the Orange Book under QVAR Redihaler the '512, '889, '637, and '643 patents; and
- Refrained from listing in the Orange Book under QVAR the '808, '512, and '889 patents.
- Refrained from suing within forty-five days of any subsequent Paragraph IV certification, thereby ensuring that the mere listing would not slow down final FDA approval of a competitor's submission.

469. Had Teva followed the law, there would be no patents listed in the Orange Book as claiming QVAR, and, in spring 2020, no patents listed in the Orange Book as claiming QVAR Redihaler. Generic competitors would have been more motivated, and sooner, to seek permission to make, market, and sell generic versions of QVAR, and possibly even QVAR Redihaler. No would-be generic competitor would have had to make a paragraph IV certification. There would have been no threat of patent infringement suit from which Teva could leverage a pay for delay settlement; no lawsuits against would-be generic competitors; no thirty-month litigation delay in the approval of competitors' generic products; no ability to bottleneck the market. Generic companies could come to the market as soon as they obtained approval. This would have resulted in substantial savings to those who paid all or a portion of the cost of inhalers containing beclomethasone dipropionate (i.e., QVAR, QVAR

Redihaler, generic QVAR, and generic QVAR Redihaler), including the plaintiffs and members of the class.

470. But that is, unfortunately, not what happened.

9. Spring 2020: two other generic applicants—Cipla and Aurobindo—filed ANDAs, seeking approval to sell QVAR.

471. In the spring of 2020, after Amneal filed its generic QVAR ANDA, two more generic companies filed QVAR ANDAs.

i. Cipla Ltd. filed an ANDA, and notified Teva that it had filed paragraph IV certifications as to each of the improperly listed QVAR patents.

472. First, Cipla Ltd. ("Cipla") filed a generic QVAR ANDA sometime in late May or early-to mid-June 2020. The Cipla ANDA contained paragraph IV certifications to all of the patents then listed in the Orange Book: the '289 patent, the '587 patents, the '509 patent, '510 patent, the '156 patent, and the '808 patent.

473. Cipla notified Teva of its paragraph IV certifications in a letter sent June 24, 2020.

474. In July 2020, Teva listed the '512 patent in the Orange Book. On September 8, 2020, Cipla amended its ANDA, and submitted a second notice to Teva, advising the defendants that Cipla had added a paragraph IV certification as to that newly listed patent as well.

ii. Aurobindo Pharma Ltd. filed an ANDA, and notified Teva that it had filed paragraph IV certifications as to each of the improperly listed QVAR patents.

475. Second, Aurobindo Pharma Ltd. ("Aurobindo") and two of its subsidiaries filed a generic QVAR ANDA in late August or early September 2020. The

Aurobindo ANDA contained paragraph IV certifications to all of the patents then listed in the Orange Book: the '289 patent, the '587 patent, the '509 patent, the '510 patent, the '156 patent, the '808 patent, and the '512 patent.

10. August 2020 – present: Teva institutes and maintains sham litigation against Cipla and Aurobindo.

476. As noted above, if Teva's aim was to comply with the antitrust laws—and even if the *Lantus* decision did not give an unequivocal mandate that Teva's patents were not properly listable—it could have listed, but not sued within forty-five days of any subsequent Paragraph IV certification notice over its inhaler device patents thereby ensuring that the mere listing would not slow down FDA approval of a competitors' submission.

477. But Teva's goal was not to comply with the antitrust laws; its goal was to delay generic QVAR competition and unlawfully preserve its monopoly in the market for QVAR and QVAR Redihaler.

478. On August 7, 2020, Teva sued Cipla in the United States District Court for the District of New Jersey alleging that Cipla infringed the '289 patent, the '587 patents, the '509 patent, the '510 patent, the '156 patent, and the '808 patent.

479. On October 22, 2020, Teva sued Aurobindo in the District of New Jersey, alleging that Aurobindo infringed the '289 patent, the '587 patent, the '509 patent, the '510 patent, the '156 patent, the '808 patent, and the '512 patent.

480. On October 23, 2020, Teva filed a second complaint against Cipla in the District of New Jersey alleging that Cipla infringed the '512 patent.

481. All three lawsuits were consolidated on January 8, 2021.

482. Teva should never have sued either company within forty-five days of their respective Paragraph IV certification notice since none of the asserted patents "claim[ed] the drug" QVAR or its active ingredient beclomethasone dipropionate,[11] so a reasonable drug company in Teva's position would have known that they did not have standing to preemptively sue Cipla or Aurobindo for infringing Teva's device patents.

483. But Teva did not sue Cipla and Aurobindo in a good faith effort to protect valid and valuable intellectual property properly listed in the Orange Book. Instead, Teva sued to prevent generic competition and, more importantly, to keep Cipla or Aurobindo from triggering Amneal's obligation to launch or forfeit its exclusivity.

i. All of the claims Teva asserted in the *Cipla* and *Aurobindo* litigations claimed an inhaler device, or just a portion of an inhaler device.

484. Teva asserted that Cipla and Aurobindo each infringed claim 1 of the '289 patent.

485. Claim 1 of the '289 patent reads:

> An inhaler for metered dose inhalation, the inhaler comprising:
>
> a main body having a canister housing,
>
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

[11] *See supra* Section V.B.6.

> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
>
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and
>
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,
>
> the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

486. Teva alleged that Cipla and Aurobindo each infringed claims 1, 12, and 13 of the '587 patent.

487. Claim 1 of the '587 patent reads:

> An inhaler for metered dose inhalation, the inhaler comprising:
>
> a main body having a canister housing,
>
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
>
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
>
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
>
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and
>
> wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in

a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.

488. Claim 12 of the '587 patent reads:

An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,

wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,

wherein the canister housing has a longitudinal axis x which passes through the center of the central outlet port, and

wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.

489. And claim 13 of the '587 patent reads:

An inhaler for metered dose inhalation, the inhaler comprising:

a main body having a canister housing,

> a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
>
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
>
> wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

490. Teva alleged that Cipla and Aurobindo each infringed claim 1 of the '509 patent.

491. Claim 1 of the '509 patent reads:

> A dose counter for an inhaler, the dose counter having a display tape arranged to be incrementally driven from a tape stock bobbin onto an incremental tape take-up drive shaft, the bobbin having an internal bore supported by and for rotation about a support shaft, at least one of the bore and the support shaft having a radially extending protrusion having a leading portion edge, a trailing portion edge, wherein at least one of the leading portion edge and the trailing portion edge are tapered, and a friction edge between the leading portion edge and the trailing portion edge, wherein the friction edge is substantially parallel to a longitudinal axis of the support shaft and the leading portion edge and trailing portion edge are not parallel to the longitudinal axis of the support shaft, and the friction edge is resiliently biased into frictional engagement with the other of the bore and support shaft with longitudinally extending mutual frictional interaction and wherein the friction edge extends further in a longitudinal direction than the protrusion extends radially.

492. Teva alleged that Cipla and Aurobindo each infringed claims 1, 10, and 20 of the '510 patent.

493. Claim 1 of the ’510 patent reads:

> An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:
>
> > a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure, a tape size marker located on the main elongate tape structure indicating a number of dosing indicia on the main elongate tape structure, and priming indicia located on the main elongate tape structure, the priming indicia being located between the dosing indicia and a first end of the main elongate tape structure and visible in the dose counter viewing window before priming before first use, and
> >
> > wherein the first end of the main elongate tape structure is fixed to a tape reel shaft and a second end of the main elongate tape structure is attached to a stock bobbin, and wherein the main elongate tape structure is around both the stock bobbin and tape reel shaft when the priming indicia is visible in the dose counter viewing window before priming before first use.

494. Claim 10 of the ’510 patent reads:

> An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:
>
> > a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure, and a tape size marker located on the main elongate tape structure indicating a number of dosing indicia on the main elongate tape structure, wherein the tape size marker is positioned between a first end of the main elongate tape structure and the tape positioning indicia,

wherein the first end of the main elongate tape structure is fixed to a tape reel shaft and a second end of the main elongate tape structure is attached to a stock bobbin, and wherein the tape is around both the stock bobbin and tape reel shaft and a portion of the main elongate tape structure between the tape positioning indicia and the dosing indicia is visible in the dose counter viewing window before priming before first use.

495. Claim 20 of the '510 patent reads:

An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:

a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure so as to be visible in the dose counter viewing window before priming before first use, and priming indicia located on the main elongate tape structure, the priming indicia being located between the tape positioning indicia and the dosing indicia,

wherein a first end of the main elongate tape structure is attached to a stock bobbin and a second end of the main elongate tape structure is fixed to a tape reel shaft, and wherein the main elongate tape structure is around both the stock bobbin and tape reel shaft when the priming indicia is visible in the dose counter viewing window before priming before first use.

496. Teva alleged that Cipla and Aurobindo each infringed claim 1 of the '156 patent.

497. Claim 1 of the '156 patent reads:

A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:

> a ratchet wheel having a plurality of circumferentially spaced teeth,
>
> an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,
>
> a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth, and
>
> a dosage indicator associated with the count pawl,
>
> wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth,
>
> wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count,
>
> wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.

498. Teva alleged that Cipla and Aurobindo each infringed claim 1 of the ’808 patent.

499. Claim 1 of the ’808 patent reads:

> A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a

> second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

500. And Teva alleged that Cipla and Aurobindo each infringed claim 1 of the '512 patent.

501. Claim 1 of the '512 patent reads:

> An inhaler for inhaling medicament, the inhaler having:
>
> A body for retaining a medicament canister; and
>
> a dose counter, the dose counter having a moveable actuator and a chassis mounted on the body;
>
> wherein one of the body and the chassis includes a plurality of apertures for receiving one or more pins on the other of the body and the chassis,
>
> wherein either the pins or the apertures on the chassis are positioned on different sides of the chassis for stabilizing the chassis on the body, and
>
> wherein the chassis comprises at least one of a pin or aperture heat staked to a respective aperture or pin of the body to mount the chassis to the body.

ii. Teva did not avail itself of Cipla's nor Aurobindo's offer to review their respective ANDA's and proposed inhaler devices prior to initiating suit posed inhaler devices infringed Teva's and Norton's device-only patents.

502. Each of the patents that Teva had listed in the Orange Book (and alleged that Cipla and Aurobindo infringed) claimed an inhaler containing a dose counter, or just a dose-counter mechanism for an inhaler device.

503. The inhaler devices that Cipla and Aurobindo proposed to use with their generic QVAR products included a dose-counter mechanism.

504. As far as Teva was concerned, that was reason enough to sue.

505. Cipla offered Teva the opportunity to confidentially review portions of its ANDA, along with samples of its proposed inhaler device so that Teva could review in good faith whether Cipla's product actually infringed Teva's patents. Teva refused to accept the offer and just sued instead.

506. Aurobindo, too, offered Teva confidential access to its application materials. But again, Teva did not take the opportunity to review the materials and evaluate whether it had a good faith and reasonable basis to sue. It just sued.

507. Had Teva reviewed Cipla's and Aurobindo's ANDA offerings, it would have learned that beyond doubt neither company's inhaler infringed all of the asserted patents: both companies had proposed to use inhalers with dose counters radically different than the dose counter described in Teva's device patents.

508. Take the '509 and '510 patents as an example. Both Cipla and Aurobindo proposed to use an inhaler device with a gear-based dose-counter. Gear-based dose counters operate by turning a gear one click with each use. Doing so rotates a second gear with a counter on it that counts down the number of doses remaining in the cannister.

509. Teva's '509 and '510 device patents do not claim a gear-based dose counter.

510. Instead, they claim a tape-based dose-counter.

511. Had Teva examined, in good faith, Cipla's or Aurobindo's paragraph IV notices and offered ANDA products, it would have determined that neither product infringed the '509 or '510 patents.

512. Cipla moved for judgment on the pleadings,[12] arguing that Teva's suit "should never have been filed because Cipla's ANDA Product does not infringe any asserted patent," and, if Teva "tr[ied] to construe any claims to cover Cipla's ANDA Product, those claims would be invalid as covering the prior art."

513. In opposition, Teva argued that, simply because Cipla filed an ANDA, Teva was *entitled* to a two-and-a-half-year-long litigation process, and that therefore, the court should deny Cipla's motion:

> An abbreviated new drug application ("ANDA") is fundamentally a compromise; it offers a streamlined regulatory process in exchange for a thirty-month stay of approval while a court adjudicates accelerated claims of patent infringement. Having taken advantage of the former, Cipla may not decline to participate in the latter, statutorily-prescribed [sic] litigation.

In other words, Teva argued that whatever the merit of Cipla's motion for judgment on the pleadings, Cipla must wait for two and a half years to adjudicate the issue.

514. Teva's argument is flat wrong. Under the FDCA, Teva is not *guaranteed* two and a half years of delay just because it filed suit (over its wrongfully listed patents). Rather, the statute provides that, a suit over a paragraph IV certification stays FDA approval *until the earlier of* (a) two and a half years or (b) *a court decision finding that the patent is invalid or not infringed*. Option "b" has no timeframe: the

[12] The court does not appear to have ruled on Cipla's motion.

court decision can come from a ruling after trial, or at summary judgment, or even—as Cipla sought—on the pleadings. And it is entitled to no litigation stay at all unless it has valid, objectively reasonable claims that it presses in good faith.

515. Teva's argument is noteworthy for another reason: it betrays Teva's intent to leverage its litigations to create delay. If Teva were interested in the actual benefits the Hatch-Waxman litigation framework provides—streamlined resolution of patent disputes—it would welcome adjudication on the pleadings. But that was not what Teva wanted: Teva wanted delay.

iii. Teva's litigation tactics were focused on delay, not success.

516. Although Teva initially sued both Cipla and Aurobindo over seven patents each, once it had assured itself a delay in competition while the supposed patent disputes played out, it readily abandoned some claims.

517. On June 1, 2021, Teva and Cipla stipulated to the dismissal of Teva's infringement claims as to the '509 and '510 patent (and Cipla's counterclaims of non-infringement and invalidity).

518. On May 31, 2022, and June 6, 2022, Teva stipulated with Aurobindo and Cipla, respectively, to dismiss Teva's infringement claims as to the '512 patent (and Aurobindo's and Cipla's counterclaims). In doing so, Teva expressly stipulated that the generic companies' products did not infringe the patent.

519. On September 21, 2022, Teva and Aurobindo stipulated to the dismissal of Teva's infringement claims (and Aurobindo's counterclaims) as to the '156 patent. Again, Teva expressly stipulated that Aurobindo's product did not infringe the patent.

520. On October 11, 2022, Teva and Aurobindo stipulated to the dismissal of their claims as to the '509 and '510 patents.

521. Around the same time, Teva offered Cipla a covenant not to sue for infringement of Teva's '156 patent, if Cipla dismissed its corresponding counterclaims. But this offer was never memorialized in a stipulation because the parties disagreed on the language to be used. Specifically, Teva refused to include language referencing a finding of non-infringement.

522. On October 31, 2022, Teva filed a motion to dismiss Cipla's claims and counterclaims as to the '156 patent, claiming that the court lacked subject matter jurisdiction over the claims.

523. Teva argued that its covenant not to sue stripped the court of subject matter jurisdiction to adjudicate the parties' claims in connection with the '156 patent. Ordinarily, a covenant not to sue would not strip a court of jurisdiction over related counterclaims: in the Hatch-Waxman context, the court could retain jurisdiction so long as a judgment for the defendant on its counterclaims could trigger a first-filer's obligation to sue.

524. But, as Teva told the court, there were at least *three* patents that blocked Amneal from launching: the '509 patent, '510 patent, and '156 patent. Because Cipla had already stipulated to dismissing its '509 and 510 patent claims, Teva argued, even a judgment for Cipla on its '156 patent counterclaims would not break the bottleneck to generic entry. The district court agreed, and dismissed Cipla's '156 patent counterclaims.

525. That admission, when viewed against Teva's prior stipulations in the patent case, reveals its strategy. Teva freely gave stipulations of non-infringement for certain patents, but not those that were impeding Amneal—namely the '509 patent, '510 patent, and '156 patent:

Asserted Patents	Dismissed as to		Non-infringement Stipulation as to	
	Cipla	Aurobindo	Cipla	Aurobindo
'289 patent				
'587 patent				
'509 patent	6/1/2021	10/11/2022	*no*	*no*
'510 patent	6/1/2021	10/11/2022	*no*	*no*
'156 patent	11/11/2022	9/21/2022	*no*	yes
'808 patent				
'512 patent	6/6/2022	5/31/2022	yes	yes

526. By suing over, and then declining to stipulate with Cipla that Cipla's generic product did not infringe the '509 patent, '510 patent, and '156 patent, Teva was able to maximize the delay in generic entry. Teva took full advantage of its ability to delay generic competition for two and a half years simply by suing; and then (as those two and a half years ran out) ensured that, regardless of the substantive outcome of the remaining patent disputes, the case would not curtail its ability to delay competition.

527. And because of Teva's machinations, it gained the ability to delay generic QVAR competition indefinitely.

528. Teva knew this based on its own experience as a generic company.

529. Years earlier, Teva was the first-filer for another drug, Kytril (granisetron hydrochloride). It filed a paragraph IV certification to one Orange Book-

listed patent. The brand-name drug maker did not sue Teva for patent infringement, nor did it sue the later ANDA filers. And neither Teva nor any other generic applicant sought a declaratory judgment that the relevant patent was invalid or not infringed. After Teva's generic Kytril ANDA received approval, the question arose: by what date would Teva need to launch to avoid forfeiting its first-filer exclusivity?

530. The FDA determined that Teva *could not* forfeit its exclusivity because there was no litigation over the relevant patent. Starting from the plain language of the statute, the agency explained that

> Application of the 'failure to market' forfeiture provisions in section 505(j)(5)(D)(i)(I) requires a series of earlier-of/later-of analyses. The statute directs that a forfeiture event occurs when the first applicant fails to market the drug by the later of two dates.

The first of those two dates (the "(aa) date") "is calculated . . . by determining the earlier of . . . 75 days after the first applicant's ANDA is approved or . . . 30 months after the date of submission of the first applicant's ANDA." The second date (the "(bb) date") is the later of the dates on which:

> (a) a court enters a final decision that the patent is invalid or not infringed, (b) a court signs a settlement order or consent decree entering final judgment that includes a finding that the patent is invalid or not infringed, or (c) the patent information for the listed drug is withdrawn by the NDA holder.

531. Applying this rule to Teva's generic Kytril situation, the FDA determined that the (aa) date was December 1, 2006, thirty months after Teva filed its ANDA. But given that neither Teva nor any other generic Kytril applicant was embroiled in litigation over the Kytril patents, there was *no* (bb) date.

532. The FDA determined that, under those circumstances, a first-filer's exclusivity could never be forfeited. In reaching this conclusion, the FDA acknowledged a loophole in the drug laws:

> Inherent in the structure of the "failure to market" forfeiture provisions is the possibility that a first applicant would be able to enter into a settlement agreement with the NDA holder or patent owner in which a court does not enter a final judgment of invalidity or non-infringement (i.e., without [(bb) date] occurring), and that subsequent applicants would be unable to initiate a forfeiture with a declaratory judgment action. This inability to force a forfeiture of 180-day exclusivity could result in delays in the approval of otherwise approvable ANDAs . . . . *This potential scenario is not one for which the statute currently provides a remedy*.

533. By choosing not to sue Amneal and then ensuring that the patents blocking Amneal could not be adjudicated in the Cipla and Aurobindo litigation, Teva manufactured a regulatory quandary analogous to Kytril, assuring that Amneal's obligation to either launch or forfeit could not be triggered.

534. For Amneal, the (aa) date was July 10, 2022, thirty-months after it filed its ANDA. Because Teva (i) did not sue Amneal and (ii) stripped the *Teva v. Cipla* court of jurisdiction over three key patents blocking Amneal, there could be no court decision or settlement finding those patents invalid or not infringed, and, thus, no (bb) date for Amneal.

535. In the generic Kytril situation, the FDA noted, there was no evidence that Teva was trying to "park[]" its exclusivity "as a result of" a pay-for-delay agreement "with the NDA holder and/or patent owner." Here, in contrast, there is

evidence that Teva *was* in fact trying to (and successfully did) delay generic competition for QVAR.

11. Date unknown: Teva entered into an agreement with Amneal to delay generic QVAR competition for an unknown amount of time.

536. As Cipla argued against Teva's motion to dismiss its '156 patent counterclaims, Cipla acknowledged that it had agreed to dismissal of its '509 patent and '510 patent counterclaims because it believed that Amneal would have launched before late 2022—a reasonable assumption since Amneal had publicly represented that it planned to launch in 2021.

537. To date, Amneal still has not launched its generic QVAR product—more than three years after filing its ANDA, and two years after telling the investing public it would.

538. The circumstances regarding Amneal's continued absence from the market suggest that Teva reached an agreement with Amneal to delay its launch—thereby delaying all competition with its blockbuster QVAR franchise in exchange for some form of valuable consideration passing from Teva, the patent holder, to Amneal, the patent challenger. The exact form of consideration is unknown but can take any one or more forms including, for example, cash payments, favorable marketing deals on other products, favorable consulting arrangements, and agreements not to compete with an authorized generic when generic entry finally occurs.

539. When Amneal submitted its application on January 10, 2020, it provided paragraph IV certifications to *all* of Teva's listed patents related to QVAR. Otherwise, Amneal could not have represented to investors that it intended to come

to market in 2021. Each of the QVAR-related patents listed in the Orange Book at the time expired in 2031. Had Amneal filed a paragraph III certification as to even one of those patents, it would have been barred from the market for a decade.

540. Teva did not sue Amneal within 45 days of receiving the first-filer's paragraph IV notice. Indeed, Teva did not sue Amneal at all. Because Teva did not sue, it could not trigger a delay in Amneal's launch of up to 30 months, and Amneal was free to come to the market as soon as it could obtain FDA approval for its product.

541. In addition, Amneal did not experience any hold-ups with the FDA during the agency's substantive review of its application.

542. If this were the whole story, then under the FDCA, the FDA's regulations, and the agency's practices, Amneal would have obtained approval for its drug within thirty months after filing its application—i.e., by July 10, 2022. The FDA would have assured that its substantive review was complete, such that it could issue an approval by that deadline.

543. And Amneal would have been incentivized to launch as soon as possible thereafter—particularly because the other generic applicants, Cipla and Aurobindo, were tied up in litigation, which would prevent them from launching competing generic products until December 2022 and April 2023, respectively. Had Amneal obtained approval in 2021, as it expected, and launched, it would have been able to enjoy much more than just 6 months of lucrative generic exclusivity.

544. But subsequent developments show that, behind the scenes, something more was going on.

545. For example, by late 2020 and early 2021, Amneal first hedged on its prior representations that it expected a 2021 launch, saying that it would launch generic QVAR (and other unspecified inhaler products) sometime between 2021 and 2025. Thereafter, Amneal fell silent about the application, declining to mention it in either its SEC filings or in calls with investors.

546. Amneal did not launch generic QVAR in 2021 or 2022. Indeed, as of the date of this Complaint, Amneal has not launched its generic QVAR product.

547. Teva's own admissions at the final pretrial conference in the *Teva v. Cipla* matter shed some light on why. At the conference on November 10, 2022, Teva told the court (and Cipla) that at least three patents were blocking Amneal from coming to market: the '509 patent, the '510 patent, and the '156 patent.

548. A patent can block a generic company from coming to market in the following three scenarios: (1) the generic drugmaker files a paragraph III certification, thereby promising to wait out the expiry of the patent before launching; (2) the brand-name drugmaker obtains a judgment in a Hatch-Waxman patent suit that the patent is valid and infringed; and (3) the generic company and the brand-name drugmaker enter into an agreement stipulating that the patent is valid and infringed.

549. Scenario 1 cannot be the case here. Amneal did not file any paragraph III certifications when it submitted its generic QVAR ANDA. It encountered no manufacturing issues that would have raised concerns about its ability to obtain timely approval. And it would have been incentivized to launch as soon as possible,

as it had promised its investors, to take the greatest advantage of its exclusivity in the marketplace. It would not have revised any of its patent certifications from paragraph IV certification to a paragraph III certification (absent some significant incentive to do so).

550. Scenario 2 is also impossible. Because Teva did not sue Amneal for patent infringement, and because it ensured neither Cipla nor Aurobindo could obtain a judgment on the '509 patent, '510 patent, or '156 patent, there could be no judgment of non-infringement or invalidity.

551. That leaves scenario 3 as the only plausible explanation for the facts as they exist: Teva and Amneal reached an agreement that induced Amneal to quit its plans to launch in 2021 and to delay its launch until possibly 2025 or even beyond.

552. Typically, those agreements come in the form of a settlement agreement resolving a lawsuit. But as Teva well knew, a settlement *outside of the litigation process* presents better opportunities to delay, because if there is no litigation in which a judgment can be entered or a settlement reached, then there is no limit on how long a first-filer can delay.

553. Scenario 3 also explains why there has been no approval of Amneal's ANDA or any announcement that Amneal has forfeited its exclusivity. By reaching an agreement outside of the litigation context, Teva ensured that there was no (bb) date—i.e., no date of a final judgment of invalidity or non-infringement or a settlement agreement allowing for generic entry—that would require Amneal to either launch or forfeit exclusivity. Accordingly, there is no forfeiture date when

Amneal must launch its product. With no impending deadlines or forfeiture dates, the FDA has prioritized other, more time-sensitive applications.

554. In its second quarter 2023 earnings presentation and call with investors, Cipla acknowledged, for what appears to be the first time, that it was the QVAR first-filer. And it disclosed that it would not be bringing its generic QVAR version to market until 2024.

12. November – December 2022: Teva engages in a trial against Cipla and settles with Aurobindo.

555. From November 16 to 18, 2022, Teva and Cipla held a bench trial in the U.S. District Court for the District of New Jersey limited to certain claims of the '289, '587, and '808 patents.[13]

556. In the ways that matter, the trial was an act in futility. Because Teva excised from the case those patents that blocked Amneal's exclusivity, a judgment of non-infringement or invalidity in Cipla's favor on any of the patents left in the case could not trigger Amneal's obligation to launch or forfeit exclusivity.

557. Perhaps because of that futility, Aurobindo settled with Teva on December 22, 2022. Teva and Aurobindo have kept the terms of their settlement secret.

558. On June 21, 2023, the district court issued its opinion finding that on the preponderance of evidence standard Cipla's ANDA product infringes each of the

[13] At trial, Teva asserted Cipla infringed independent claim 1 and dependent claims 2, 4, 6, and 7 of the '289 patent, independent claims 1 and 12, and dependent claims 2, 4, 6, and 7 of the '587 patent, and dependent claim 28 which depends from claims 1 and 27 of the '808 patent.

asserted claims of the '289, '587, and '808 patents and that on the clear and convincing evidence standard Cipla had not proven those patents were invalid.

559. In rendering its opinion, the district court acknowledged that Cipla had valid challenges to the validity and infringement of Teva's patents, but did not credit them because, the Court found, Cipla's expert through whom those challenges did not provide sufficient details to support such challenges.

560. The Court relied heavily on the testimony provided by the parties' respective competing expert witnesses and, in general, favored the testimony provided by Teva's expert over the testimony provided by Cipla's expert, sometimes to the exclusion of other valid evidence. For example, the district court recognized Cipla had valid challenges to the experiments conducted by Teva's expert. It noted that the experiments that Teva's expert performed "may not be perfect tests to prove an 'airtight' infringement case," and that Teva's expert "could have performed better experiments to support his conclusions." However, it discounted Cipla's noninfringement defense because Cipla's expert did not conduct his own tests.

561. Concerning invalidity, the district court accepted Teva's argument that Cipla had failed to prove that a person of ordinary skill in the art would have selected the prior art references Cipla relied on to show the asserted patent claims were invalid. But in doing so, it ignored the fact that Teva's own expert conceded the dose counter in the principal prior art reference – International Patent Publication No. WO 2007/124406 – relied upon by Cipla 'looks the same' as the dose-counter used in Cipla's product. The district court also apparently discounted Cipla's expert's

discussion of the state of the art at the time of the invention showing why there was a motivation to select and combine the prior art Cipla relied upon to challenge the validity of the asserted patent claims.

562. Cipla has timely filed a notice of appeal of the district court judgment to the United States Court of Appeals for the Federal Circuit. There are strong indications—such as the district court's failure to acknowledge some of the evidence Cipla elicited and key concessions made by Teva's own expert—that the district court judgment will not be affirmed.

563. Regardless, the outcome of the *Cipla* litigation does not indicate that Amneal (or another company) could not prevail in showing Teva's patents invalid or not infringed. First, patents are never held "valid" and are only found "not invalid" over the facts and arguments presented.[14] Second, the fact that, according to the district court in *Cipla*, Cipla's product infringed Teva's patent does not mean that Amneal's product would also infringe.[15]

564. And third, the district court's decision hinged upon its assessment of Cipla's expert's credibility. It acknowledged the persuasive force of several arguments Cipla made, yet did not credit those arguments because the supporting proof came from a witness the court found not credible. Another generic drug company,

[14] *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 994 (Fed. Cir. 2009) (Courts "do not declare patents to be valid"; they "only declare that they have not been proved to be invalid . . . ."); *Shelcore, Inc. v. Durham Indus., Inc.*, 745 F.2d 621, 627 (Fed. Cir. 1984) ("A patent is not held valid for all purposes, but, rather, not invalid on the record before the court.").

[15] *Fantasy Sports v. Sportsline.com*, 287 F.3d 1108, 1117-18 (Fed. Cir. 2002) ("[I]n every infringement analysis, the language of the claims, as well as the nature of the accused product, dictates whether an infringement has occurred.").

presenting the same case through a more credible witness, would likely prevail in showing that Teva's patents could not bar overdue generic competition.

13. Teva plans to prolong its unlawful monopoly even further with a second product hop.

565. So far, Teva's anticompetitive scheme, as set forth above, has delayed availability of affordable generic QVAR for as much as five years (and counting) beyond the life of its latest-expiring lawfully listed drug product patent. But for Teva, that is not enough.

566. Teva has announced that it intends to execute a *second* product hop in its QVAR franchise in the coming years.

567. Since launching QVAR Redihaler, Teva developed a new inhaler in 2020, called the Digihaler. The Digihaler is a "smart" inhaler "with built-in sensors that automatically capture objective inhaler use data" and shares that information with an app on the patients' phone.

568. Teva already uses the Digihaler with some of its other respiratory products, such as ProAir (albuterol sulfate). Since obtaining approval for its ProAir Digihaler in January 2019, Teva has listed *twenty-two* patents in the Orange Book as claiming ProAir Digihaler. The expiry dates on these patents extends as far as 2041.

569. In its recent Fiscal Year 2022 SEC filing, Teva has announced its intention to combine its Digihaler device with its QVAR drug product. Teva disclosed that QVAR Digihaler is in the "pre-submission" phase of development—meaning that clinical trials are complete, but Teva has not yet submitted an NDA or a supplemental NDA to the FDA asking for approval.

570. If Teva's anticompetitive scheme is allowed to continue—if it can stave off generic competition long enough to switch its product once more from the QVAR Redihaler to a QVAR Digihaler—it could thwart competition for almost two more decades, stretching its anticompetitive generic delay to a whopping 26 years.

VI. EFFECTS OF THE SCHEME ON COMPETITION AND DAMAGES TO THE PLAINTIFFS AND THE CLASS

571. Teva's scheme to thwart competition has proved lucrative for the company. It has sold approximately $6.2 billion in QVAR and QVAR Redihaler products since 2015. This is hundreds of millions, if not billions of dollars more in sales that Teva could have made if it had not engaged in a sweeping scheme to impair competition. If Amneal's generic product had entered the market in 2021, it would have driven prices down and eroded Teva's market share. And if Teva had not stuffed the Orange Book with unlistable device patents starting in 2014, a generic company may have been able to file an ANDA even earlier, resulting in earlier price decreases and erosion.

572. Teva's anticompetitive scheme impaired and delayed the sale of affordable generic versions of QVAR in the United States, freeing Teva to sell QVAR and QVAR Redihaler at artificially high prices.

573. But for Teva's anticompetitive conduct, at least one generic manufacturer would have entered the marketplace and competed with Teva's brand-name QVAR by 2021 at the latest—and more likely as early as 2015, when Teva's only lawfully listed drug product patent expired. At least one and possibly two more generic competitors would have entered the marketplace six months later.

574. Consequently, but for Teva's anticompetitive conduct, the plaintiffs and other members of the class would have been able to (a) purchase generic QVAR products instead of Teva's expensive QVAR and QVAR Redihaler products for some or all their beclomethasone dipropionate HFA needs; and (b) paid a lower price for their beclomethasone dipropionate HFA needs.

575. Had Teva not engaged in anticompetitive conduct, the market would have embraced generic QVAR—which is just as safe and effective as QVAR and QVAR Redihaler at a fraction of the price. Because of state substitution laws, generic QVAR products would have captured 90% of the market, and ushered in substantial cost savings to the plaintiffs and members of the class. As a result of Teva's anticompetitive scheme, however, generic competition for QVAR and QVAR Redihaler have been completely thwarted.

576. During the relevant period, the plaintiffs and other purchasers paid for substantial amounts of QVAR and QVAR Redihaler; the prices the plaintiffs and other third-party payors paid for prescriptions of these products was substantially greater than the prices they would have paid but for the unlawful conduct alleged herein.

577. As a result, the plaintiffs and other third-party payors have incurred substantial losses, the exact amount of which will be the subject of proof at trial.

VII. MARKET POWER AND MARKET DEFINITION

578. Teva wrongfully acquired, locked in, and exploited monopoly power in the market for beclomethasone dipropionate HFA products. At all relevant times, it had the power to raise or maintain the price of QVAR and QVAR Redihaler to supra-

competitive level without losing enough sales to make supra-competitive prices unprofitable.

579. At all relevant times to this case, there were other inhaled corticosteroid medications for asthma maintenance available in the market, including, for example, Flovent Diskus and Flovent HFA (fluticasone) and Pulmicort Flexhaler (budesonide). But none of these other asthma maintenance medications were equivalent to one another, nor were they equivalent to QVAR or QVAR Redihaler.

580. The other products contained different drug substances (active ingredients): each contained a different molecule with a different mechanism of action.

581. At all relevant times, QVAR and QVAR Redihaler were the only products on the market that contained the active ingredient beclomethasone dipropionate.

582. A small but significant, non-transitory price increase to the price of QVAR or QVAR Redihaler would not have caused a significant loss of sales.

583. QVAR and QVAR Redihaler do not exhibit significant, positive cross-elasticity of demand with respect to the price of any other inhaled corticosteroid asthma maintenance product, other than those containing beclomethasone dipropionate.

584. Teva needed only to control QVAR and QVAR Redihaler and their generic equivalents, and no other products, in order to maintain QVAR and QVAR Redihaler supra-competitive prices profitably without losing substantial sales. The

only market event that would render Teva unable to profitably maintain supra-competitive prices would be the entry of a generic beclomethasone dipropionate HFA product.

585. Teva also sold QVAR and QVAR Redihaler at prices well above marginal costs, and in excess of competitive prices; as a result, it enjoyed high profit margins with the price more than 60% higher than the cost of production.

586. Teva has had, and has exercised, the power to exclude competition to QVAR and QVAR Redihaler.

587. Teva enjoyed, at all relevant times, high barriers to entry with respect to QVAR and QVAR Redihaler.

588. There is direct evidence of Teva's market power and the anticompetitive effects of its scheme sufficient to show Teva's ability to control the prices of, and exclude competition for, QVAR and QVAR Redihaler, without the need to define the relevant antitrust market.

589. The direct evidence includes: (a) the fact that competing beclomethasone dipropionate producers would have entered the market at a substantial discount to the price of QVAR and QVAR Redihaler but for Teva's anticompetitive conduct; and (b) the gross margin on QVAR and QVAR Redihaler were, at all times, substantial enough to show market power.

590. To the extent the plaintiffs may be required to plead and prove Teva's monopoly power by defining a relevant product market, the plaintiffs allege that the relevant antitrust market is the beclomethasone dipropionate market.

591. The United States, its territories, and the District of Columbia constitute the relevant geographic market.

592. Teva's share in the relevant market was 100% at all relevant times, continuing to today.

VIII. MARKET EFFECTS

593. Teva willfully and unlawfully maintained its market power by engaging in an overarching scheme to exclude competition. Teva designed this scheme to delay competition on the merits, for the anticompetitive purpose of thwarting, or at least delaying, competition against its QVAR product franchise. As a result of the scheme, Teva was able to maintain supracompetitive prices for QVAR and QVAR Redihaler.

594. Teva's overarching anticompetitive scheme consisted of 7 parts: (1) as the expiry over its lawful patent monopoly approached, Teva wrongfully listed two device-only patents in the Orange Book[16] to buy it more time to (2) execute a hard-switch product hop from QVAR to QVAR Redihaler.[17] Then Teva (3) stuffed the Orange Book with improper patent listings for both QVAR Redihaler (ten patents)[18] and QVAR (nine patents[19]).[20] It next (4) leveraged those improperly listed patents in litigation against Cipla and Aurobindo to improperly gain an automatic stay of FDA

[16] *See supra* § V.B.2.

[17] *See supra* § V.B.3.

[18] The improperly listed QVAR Redihaler patents were (at least) the '627 patent, the '260 patent, the '712 patent, the '476 patent, the '509 patent, the '510 patent, the '156 patent, the '512 patent, and the '889 patent.

[19] The improperly listed QVAR patents were the '627 patent, the '289 patent, the '587 patent, the '509 patent, the '510 patent, the '156 patent, the '808 patent, the '512 patent, and the '889 patent.

[20] *See supra* §§ V.B.4 & 6.

final approval of Cipla's and Aurobindo's ANDA filings;[21] (5) exploited a loophole in the forfeiture provisions to enable Amneal to park its exclusivity indefinitely.[22] And Teva (6) formed an illicit agreement with Amneal to delay generic QVAR competition to take advantage of that loophole[23] in the hopes of (7) executing another product hop that would prolong its wrongful monopoly for another two decades.[24]

595. These acts, in combination and individually, were undertaken to serve Teva's anticompetitive aims.

596. Teva's acts and practices described in this complaint had the purpose and effect of unreasonably restraining competition and injuring competition by preventing competition for Teva's QVAR franchise. They allowed Teva to wrongfully maintain its monopoly and exclude competition in the market for QVAR, QVAR Redihaler, and other beclomethasone dipropionate HFA products. This harmed the plaintiffs and other members of the class.

597. Teva's conduct has delayed competition unlawfully, and wrongfully enabled Teva to sell its QVAR and QVAR Redihaler products without competition from more affordable generic versions of the drugs. But for Teva's illegal conduct, one or more competitive beclomethasone dipropionate HFA products would have entered the market sooner.

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[21] *See supra* §§ V.B.9.i – iv, V.B.11.

[22] *See supra* § V.B.9.v.

[23] *See supra* § V.B.10.

[24] *See supra*§ V.B.12.

598. For example (but without limitation), had Teva not engaged in the unlawful conduct described in this complaint, (a) an affordable generic beclomethasone dipropionate product would have become available in or around July 2015, when the patent claiming beclomethasone dipropionate HFA expired, and in any event no later than 2021, when Amneal intended to launch (prior to Teva's unlawful agreement with the first-filer); and (b) the plaintiffs and other members of the class would have paid for fewer prescriptions of expensive brand-name QVAR and QVAR Redihaler, and instead benefitted from the availability of lower-cost generic versions of those drugs.

599. Teva's illegal scheme to foreclose competition to its QVAR franchise from competing generic inhaled beclomethasone dipropionate products caused the plaintiffs and all members of the class to pay more than they would have for prescriptions of QVAR franchise products absent the illegal conduct.

600. When a generic drug enters a previously monopolized market, they are priced below the cost of their brand-name counterparts. As more generic drugs enter the market, the price drops even further; and the price of the brand-name drug may drop slightly to try to keep some of its sales from being eroded by its new generic competitors. State substitution laws drive prescription dispensing to these less expensive generic products, for which the plaintiffs and members of the class pay less to reimburse prescriptions. Therefore, brand-name drugmakers have a financial interest in delaying the onset of generic competition.

601. Teva's unlawful conduct deprived the plaintiffs and members of the class of the benefits of competition that the state and federal antitrust laws are designed to protect.

IX. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

602. During the relevant time period, Teva sold, and will continue to sell, QVAR and QVAR Redihaler across state lines.

603. During the relevant time period, the plaintiffs and members of the class paid for substantial amounts of QVAR and QVAR Redihaler at supracompetitive prices. They will begin to pay for substantial amounts of beclomethasone dipropionate from Amneal, Cipla, Aurobindo, and any other subsequent generic competitors, once the anticompetitive effects of Teva's conduct cease.

604. As a result of Teva's illegal conduct, as described in this complaint, the plaintiffs and members of the class were compelled to pay, did pay, and will continue to pay, artificially inflated prices to reimburse prescriptions of QVAR and QVAR Redihaler.

605. During the relevant time period, Teva effected its overarching anticompetitive scheme, as described in this complaint, using the United States mail, interstate carriers, interstate and foreign travel, and interstate and foreign wire commerce.

X. CLASS ACTION ALLEGATIONS

606. The plaintiffs bring this action on behalf of itself and all others similarly situated under Federal Rule of Civil Procedure 23(a) and 23(b)(3):

> All persons or entities in the United States, its territories, and the District of Columbia who purchased or paid for QVAR, QVAR Redihaler, and/or AB-rated generic equivalents of QVAR or QVAR Redihaler from a source other than (i) the defendants or any of their subsidiaries; or (ii) any manufacturer of an AB-rated generic equivalent of QVAR or QVAR Redihaler or any of its subsidiaries at any time between the date on which generic QVAR would have become available in the absence of Teva's anticompetitive conduct and the date on which the anticompetitive effects of Teva's conduct ceases ("the class").

607. Excluded from the class are the defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

608. Members of the class are so numerous that joinder is impracticable. The plaintiffs believe that there are thousands of members in the class.

609. The plaintiffs' claims are typical of the claims of the members of the class. The plaintiffs and all members of the class were damaged by the same wrongful conduct of Teva, i.e., they paid artificially inflated prices for beclomethasone dipropionate products, including QVAR and QVAR Redihaler, and were deprived of earlier and more robust competition from more affordable generic versions of QVAR and QVAR Redihaler because of Teva's wrongful conduct.

610. The plaintiffs will fairly and adequately protect and represent the interests of the class. The interests of the plaintiffs are coincident with, and not antagonistic to, those of the class.

611. The plaintiffs are represented by counsel with experience in the prosecution of class-action antitrust litigation, with particular experience with class action antitrust litigation involving pharmaceutical products.

612. Questions of law and fact common to the members of the class predominate over questions that may affect only individual class members because Teva has acted on grounds generally applicable to the entire class, thus making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in Teva's wrongful conduct.

613. Questions of law and fact common to the class include, without limitation:

- Whether Teva unlawfully maintained monopoly power through all or part of its overall anticompetitive competition suppression scheme;
- Whether any of the following device patents claimed the drug product QVAR: the '627 patent, the '289 patent, the '587 patent, the '509 patent, the '510 patent, the '156 patent, the '808 patent, the '512 patent, or the '889 patent;
- Whether any of the following device patents claimed the drug product QVAR Redihaler: the '627 patent, the '260 patent, the '712 patent, the '476 patent, the '509 patent, the '510 patent, the '156 patent, the '512 patent, the '447 patent, the '888 patent, or the '889 patent;
- Whether Teva's device patents could lawfully be listed in the Orange Book;
- Whether Teva listed device patents in the Orange Book to frustrate competition;
- Whether Teva executed a hard-switch product hop from QVAR to QVAR Redihaler;
- Whether a brand-name drugmaker in Teva's position would have known that Teva lacked standing to bring Hatch-Waxman litigation over patents that did not claim the drug product QVAR;
- Whether a reasonable brand-name drugmaker in Teva's position would have known that Cipla and Aurobindo had

substantial noninfringement and invalidity arguments that would have preclude Teva from obtaining a preliminary injunction against Cipla and Aurobindo commercialized their ANDA products absent the automatic Hatch-Waxman stay;

- Whether Teva's litigations against Cipla and Aurobindo constituted an abuse of the litigation process because they were intended to block competition, rather than obtain certainty as to Teva's patent's invalidity or non-infringement;

- Whether Teva's litigations against Cipla and Aurobindo were intended to frustrate competition;

- Whether Teva's stipulations with Cipla and Aurobindo concerning the '509, '510, and '156 patents were intended to prevent Cipla and Aurobindo from triggering Amneal;

- Whether Teva refrained from suing Amneal because it knew it could erect a near-permanent bottleneck to generic competition by now suing;

- Whether Teva entered into, or attempted to enter into, an anticompetitive agreement with Amneal whereby Amneal agreed to temporally allocate the market for QVAR, QVAR Redihaler, and generic equivalents of QVAR or QVAR Redihaler;

- Whether Teva entered into an agreement with Amneal in which Amneal agreed to delay entering the market, thereby bottlenecking the generic market, in exchange for a large and unexplained transfer of value from Teva;

- Whether Teva intends to execute a second product hop, from QVAR Redihaler to QVAR Digihaler, to protect its monopoly over the QVAR franchise;

- Whether Teva's conduct, as described in this complaint, constitutes an overarching, anticompetitive scheme;

- Whether the elements of Teva's overarching scheme were, individually or collectively, anticompetitive and/or illegal;

- Whether there exist any legitimate procompetitive reasons for some or all of Teva's conduct;

- To the extent such justifications exist, whether there were less restrictive means of achieving them;
- Whether Teva's scheme, in whole or in part, has substantially affected interstate commerce;
- Whether Teva's scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of the plaintiffs and the members of the class;
- Whether, in the absence of Teva's anticompetitive conduct, a generic version of QVAR would have entered the market earlier;
- The date on which such earlier generic entry would have occurred;
- Whether, in the absence of Teva's anticompetitive conduct, additional generic versions of QVAR would have entered the market earlier;
- The date on which such additional generic entries would have occurred;
- Whether, as a result of Teva's anticompetitive conduct, payors were overcharged for prescriptions of beclomethasone dipropionate;
- Whether Teva's anticompetitive conduct was a substantial contributing factor in causing delayed availability of generic beclomethasone dipropionate;
- A reasonable estimate of the delay caused by Teva's wrongful conduct; and
- The quantum of overcharges paid by the class in the aggregate.

614. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Class treatment will permit a large number of similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of

evidence, effort, or expense that would occur if each action were adjudicated individually. The class mechanism will allow injured persons or entities to obtain redress on claims that could not practicably be pursued individually. These considerations in favor of class treatment substantially outweigh potential difficulties in management of this class action.

615. The plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme Under State Antitrust Laws
Against all defendants

616. The plaintiffs incorporate by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

617. As described above, from 2005 and continuing to today, Teva possessed market power in the market for inhaled beclomethasone dipropionate products, including the power to control prices in, prevent prices from falling in, and exclude competitors. No other manufacturer has sold a competing version of inhaled beclomethasone dipropionate in the United States.

618. Teva willfully and unlawfully maintained its market power in the beclomethasone dipropionate market from August 2014 through the present, by engaging in an overarching anticompetitive scheme to prevent generic versions of its QVAR and QVAR Redihaler products from entering the market. Teva obtained this market power through unlawful means, and not as a result of providing a superior product, business acumen, or historical accident.

619. Teva knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of AB-rate generic versions of QVAR and QVAR Redihaler to maintain is market power. This scheme included:

- Wrongfully causing ineligible patents to be listed in the Orange Book as QVAR drug product patents to extend Teva's monopoly from July 2015 until November 2017;
- Executing a hard-switch product hop from its legacy inhaler to one including a dose-counter in order to improperly list dose-counter patents which do not claim the drug beclomethasone dipropionate in the Orange Book;
- Executing a hard-switch product hop from QVAR to QVAR Redihaler to destroy the market for AB-rated generic equivalents of QVAR;
- Wrongfully causing device patents to be listed in the Orange Book as claiming the drug product QVAR Redihaler to frustrate would-be competitors;
- Wrongfully causing device patents to be listed in the Orange Book as claiming the drug product QVAR to frustrate would-be competitors;
- Asserting its wrongfully listed patents against would-be competitors in litigation to improperly gain an automatic stay of FDA final approval of Cipla's and Aurobindo's ANDA filings with the intent to delay generic QVAR competition;
- Manufacturing a near-indefinite bottleneck in generic QVAR competition by deliberately not suing Amneal and its duplicitous stipulations with Cipla and Aurobindo; and
- Agreeing with Amneal to delay generic competition.

620. Had Teva competed on the merits instead of unlawfully maintaining its monopoly in the market for inhaled beclomethasone dipropionate, the plaintiffs and the class members would have substituted more lower-priced generic QVAR for the higher-priced brand-name QVAR and QVAR Redihaler for some or all of their QVAR

requirements, and would have paid substantially lower prices for brand-name QVAR and QVAR Redihaler.

621. The goal, purpose, and effect of Teva's overarching anticompetitive scheme was to suppress generic competition for inhaled beclomethasone dipropionate, extend its dominance in that market, and maintain QVAR and QVAR Redihaler prices at supracompetitive levels.

622. Teva's scheme substantially harmed competition in the relevant market. There is and was no non-pretextual, procompetitive justification for Teva's actions that outweighs the scheme's harmful effects. Even if there were some conceivable justification that Teva could assert, the scheme is and was broader than necessary to achieve such a purpose.

623. But for Teva's illegal conduct, generic manufacturers of inhaled beclomethasone dipropionate would have been able to fairly compete with Teva in a full and timely manner, and the plaintiffs and class members, who are third-party payors, would have substituted lower-priced generic inhaled beclomethasone dipropionate for some or all of their QVAR and QVAR Redihaler purchases and/or paid lower prices for their branded QVAR and QVAR Redihaler purchases.

624. Through its scheme, Teva intentionally, willfully, and wrongfully maintained its market power in violation of the following state laws:

- Arizona Rev. Stat. §§ 44-1403 *et seq*., with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Arizona;
- Cal. Bus. & Prof. Code §§ 16700, *et seq*., with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in California;

- Conn. Gen. Stat. Ann. §§ 35-26, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Connecticut;

- D.C. Code §§ 28-4503, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in the District of Columbia;

- Haw. Rev. Stat. § 480, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Hawaii;

- Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*, and 740 Ill. Comp. Stat. §§ 10/3, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Illinois;

- Iowa Code § 553.4, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Iowa;

- Kan. Stat. Ann. §§ 50-112, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Kansas;

- Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Maine;

- Mass. Gen. L. ch. 93A, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Massachusetts, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Md. Code Ann. Com. Law, §§ 11-204, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Maryland;

- Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Michigan;

- Minn. Stat. §§ 325d.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Minnesota;

- Miss. Code. Ann. §§ 75-21-3, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Mississippi;

- Mont. Code Ann. § 30-14-205, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Montana;

- Neb. Code Ann. §§ 59-801, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Nebraska;

- Nev. Rev. Stat. Ann. §§ 598A.210, *et seq.*, with respect to purchases in Nevada by the plaintiffs and class members, who paid substantially higher prices for inhaled beclomethasone dipropionate products in actions and transactions occurring substantially within Nevada;

- N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New Hampshire;

- N.J. State. Ann. § 56:9-3, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New Jersey;

- N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New Mexico;

- N.Y. Gen. Bus. Law § 340 with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New York;

- N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in North Carolina;

- N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in North Dakota;

- Ore. Rev. Stat. §§ 646.705, *et seq.*, and 646.725, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Oregon;

- R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Rhode Island;

- S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in South Dakota;

- Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Tennessee;

- Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to the purchases of inhaled beclomethasone dipropionate products by plaintiffs and class members who reside in or are citizens of Utah;

- Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Vermont;

- W. Va. Code § 47-18-1, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in West Virginia;

- Wis. Stat. §§ 133.01, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Wisconsin, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby the plaintiffs and members of the class paid substantially higher prices for inhaled beclomethasone dipropionate products purchased in Wisconsin.

625. As a direct and proximate result of Teva's unlawful maintenance of market power, the plaintiffs and members of the class have been injured in their business or property by Teva's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their beclomethasone dipropionate products than they would have paid in the absence of those violations. Such injury in the form of overcharges is an injury of the type antitrust laws were designed to

prevent and remedy, and flows from that which makes Teva's conduct unlawful. The plaintiffs and members of the class are the proper entities to bring a case concerning this conduct.

626. The plaintiffs and the class seek damages and multiple damages as permitted by law for their injuries by Teva's violations of the above statutes.

627. The plaintiffs, through their counsel, have sent letters to the relevant state attorneys general as required by Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); Cal. Bus. & Prof. Code § 16750.2; Conn. Gen. Stat. Ann. §§ 35-37; 815 Illinois Compiled Statutes § 505/10a(d); Massachusetts General Laws ch. 93A § 10; Minnesota Statutes Ann. § 325D.63; Montana Code Ann. § 30-14-133; Nevada Revised Statute § 598A.210(3); New Hampshire Revised Statutes Ann. § 358-A:10; New York General Business Law § 340(4); Oregon Revised Statutes Ann. § 646.780; Rhode Island General Laws § 6.36.21; and Utah Code § 76-10-3109.

SECOND CLAIM FOR RELIEF
Monopolization Under State Antitrust Laws – Wrongful QVAR Orange Book Listings
Against all defendants

628. The plaintiffs incorporate by reference and re-allege all preceding paragraphs and allegations, as though set forth fully herein.

629. Teva willfully and unlawfully maintained its market power in the beclomethasone dipropionate market from August 2014 through the present, by submitting for listing in the Orange Book nine patents that did not claim—and in some cases did not even mention—QVAR's active ingredient, beclomethasone

dipropionate, and by failing to withdraw those listings once a federal appeals court unequivocally stated that such listings were improper.

630. Teva identified nine of the patents that it submitted to the FDA for listing in the Orange Book as claiming a drug product, as defined and required by the FDCA and the FDA's implementing regulations. Each claimed only a device. None of the claims in any of the QVAR-listed patents claimed that device in combination with QVAR's active ingredient. Accordingly, none of them claim the "drug product" QVAR, as that term is defined in 21 C.F.R. § 314.3.

631. For each of the nine patents Teva submitted, it prepared a Patent Listing Form in which its representative swore, under penalty of perjury, that the patent claimed the drug product QVAR. Those sworn statements were false.

632. Teva's submission of the QVAR Patent Listing Forms does not constitute petitioning activity protected by the First Amendment, because the submissions trigger the FDA to perform a purely ministerial function.

633. The requirements for patent listings—and the prohibition on listing device-only patents—has been plain from the language of the statute and the FDA's implementing regulations for more than two decades. Teva had no objectively reasonable basis to believe that listing patents that did not contain, within their claims, the QVAR drug substance was required by any concreate factual imperative recognized as legitimate by the FDA.

634. By submitting the QVAR patents for listing, Teva unlawfully gained the power to block competition (thus reducing output and raising prices) because the

extensive list of patents dissuaded would-be competitors from submitting an ANDA at all; forced those who persevered and filed an ANDA anyway to make paragraph IV certifications to patents to which they should not have had to so certify; gave Teva the ability to sue would-be competitors and trigger an automatic two and a half year delay in competition; and to leverage the suit (or a threat of a suit) to obtain an agreement from its would-be competitor(s) to further delay the launch of competing products.

635. Teva obtained this market power through unlawful means, and not as a result of providing a superior product, business acumen, or historical accident.

636. Had Teva competed on the merits instead of unlawfully maintaining its monopoly in the market for inhaled beclomethasone dipropionate, the plaintiffs and the class members would have substituted more lower-priced generic QVAR for the higher-priced brand-name QVAR and QVAR Redihaler for some or all of their QVAR requirements, and would have paid substantially lower prices for brand-name QVAR and QVAR Redihaler.

637. The goal, purpose, and effect of Teva's wrongful Orange Book listings was to suppress generic competition for inhaled beclomethasone dipropionate, extend its dominance in that market, and maintain QVAR and QVAR Redihaler prices at supracompetitive levels.

638. Teva's wrongful listings substantially harmed competition in the relevant market. There is and was no non-pretextual, procompetitive justification for Teva's actions that outweighs their harmful effects. Even if there were some

conceivable justification that Teva could assert, Teva's conduct is and was broader than necessary to achieve such a purpose.

639. But for Teva's wrongful listings, generic manufacturers of inhaled beclomethasone dipropionate would have been able to fairly compete with Teva in a full and timely manner, and the plaintiffs and class members, who are third-party payors, would have substituted lower-priced generic inhaled beclomethasone dipropionate for some or all of their QVAR and QVAR Redihaler purchases and/or paid lower prices for their branded QVAR and QVAR Redihaler purchases.

640. Through its wrongful listings, Teva intentionally and wrongfully maintained its market power with respect to QVAR in violation of the following state laws:

- Arizona Rev. Stat. §§ 44-1403 *et seq*., with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Arizona;
- Cal. Bus. & Prof. Code §§ 16700, *et seq*., with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in California;
- Conn. Gen. Stat. Ann. §§ 35-26, *et seq*., with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Connecticut;
- D.C. Code §§ 28-4503, *et seq*., with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in the District of Columbia;
- Haw. Rev. Stat. § 480, *et seq*., with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Hawaii;
- Ill. Comp. Stat. Ann. §§ 505/1, *et seq*., and 740 Ill. Comp. Stat. §§ 10/3, *et seq*., with respect to the plaintiffs' and class

members' purchases of inhaled beclomethasone dipropionate products in Illinois;

- Iowa Code § 553.4, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Iowa;

- Kan. Stat. Ann. §§ 50-112, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Kansas;

- Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Maine;

- Mass. Gen. L. ch. 93A, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Massachusetts, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Md. Code Ann. Com. Law, §§ 11-204, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Maryland;

- Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Michigan;

- Minn. Stat. §§ 325d.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Minnesota;

- Miss. Code. Ann. §§ 75-21-3, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Mississippi;

- Mont. Code Ann. § 30-14-205, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Montana;

- Neb. Code Ann. §§ 59-801, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Nebraska;

- Nev. Rev. Stat. Ann. §§ 598A.210, *et seq.*, with respect to purchases in Nevada by the plaintiff and class members, who paid substantially higher prices for inhaled beclomethasone dipropionate products in actions and transactions occurring substantially within Nevada;

- N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New Hampshire;

- N.J. State. Ann. § 56:9-3, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New Jersey;

- N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New Mexico;

- N.Y. Gen. Bus. Law § 340 with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New York;

- N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in North Carolina;

- N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in North Dakota;

- Ore. Rev. Stat. §§ 646.705, *et seq.*, and 646.725, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Oregon;

- R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Rhode Island;

- S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in South Dakota;

- Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Tennessee;

- Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to the purchases of inhaled beclomethasone dipropionate products by plaintiff and class members who reside in or are citizens of Utah;

- Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Vermont;

- W. Va. Code § 47-18-1, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in West Virginia;

- Wis. Stat. §§ 133.01, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Wisconsin, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby the plaintiff and members of the class paid substantially higher prices for inhaled beclomethasone dipropionate products purchased in Wisconsin.

641. As a direct and proximate result of Teva's unlawful maintenance of market power, the plaintiff and members of the class have been injured in their business or property by Teva's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their beclomethasone dipropionate products than they would have paid in the absence of those violations. Such injury in the form of overcharges is an injury of the type antitrust laws were designed to prevent and remedy, and flows from that which makes Teva's conduct unlawful. The plaintiff and members of the class are the proper entities to bring a case concerning this conduct.

642. The plaintiff and the class seek damages and multiple damages as permitted by law for their injuries by Teva's violations of the above statutes.

643. The plaintiff, through their counsel, has sent or will send letters to the relevant state attorneys general as required by Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); 815 Illinois Compiled Statutes § 505/10a(d); Massachusetts General Laws ch. 93A § 10; Minnesota Statutes Ann. § 325D.63; Montana Code Ann. § 30-14-133; Nevada Revised Statute § 598A.210(3); New Hampshire Revised Statutes Ann. § 358-A:10; New York General Business Law § 340(4); Oregon Revised Statutes Ann. § 646.780; Rhode Island General Laws § 6.36.21; and Utah Code § 76-10-3109.

THIRD CLAIM FOR RELIEF
Monopolization Under State Antitrust Laws – Unlawful Reverse Payment
Against all defendants

644. The plaintiff incorporates by reference and re-allege all preceding paragraphs and allegations, as though set forth fully herein.

645. Teva's illicit deal with Amneal constitutes a large and unjustified transfer of value from Teva to Amneal in exchange for the first-filer's promise to delay competition and bottleneck the market.

646. Such arrangements have been found to be an antitrust violation by the Supreme Court. That is so because they constitute a continuing illegal contract, combination, and restraint of trade, the purpose and effect of which was to (a) delay entry of generic QVAR in order to lengthen the period in which Teva could monopolize the market and gather anticompetitive profits; and (b) raise and maintain the prices that the plaintiff and members of the class would pay to supracompetitive levels to today and continuing into the future.

647. This reverse payment agreement covered a sufficient percentage of the market to harm competition.

648. As a result of the agreement between Teva and the QVAR first filer, Teva was able to bottleneck the market for generic QVAR—potentially indefinitely.

649. Teva's reverse payment substantially harmed competition in the relevant market. There neither existed nor exists any legitimate, non-pretextual, no procompetitive benefit to the arrangement between Teva and Amneal. Even if Teva could postulate a procompetitive justification on a *post hoc* basis, that pretextual procompetitive benefits would not outweigh the anticompetitive effects of the deal. And there exist less restrictive means of accomplishing any such (hypothetical) justification.

650. Through its reverse payment, Teva intentionally and wrongfully maintained its market power with respect to QVAR and QVAR Redihaler in violation of the following state laws:

- Arizona Rev. Stat. §§ 44-1403 *et seq*., with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Arizona;
- Cal. Bus. & Prof. Code §§ 16700, *et seq*., with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in California;
- Conn. Gen. Stat. Ann. §§ 35-26, *et seq*., with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Connecticut;
- D.C. Code §§ 28-4503, *et seq*., with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in the District of Columbia;

- Haw. Rev. Stat. § 480, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Hawaii;

- Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*, and 740 Ill. Comp. Stat. §§ 10/3, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Illinois;

- Iowa Code § 553.4, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Iowa;

- Kan. Stat. Ann. §§ 50-112, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Kansas;

- Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Maine;

- Mass. Gen. L. ch. 93A, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Massachusetts, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Md. Code Ann. Com. Law, §§ 11-204, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Maryland;

- Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Michigan;

- Minn. Stat. §§ 325d.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Minnesota;

- Miss. Code. Ann. §§ 75-21-3, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Mississippi;

- Mont. Code Ann. § 30-14-205, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Montana;

- Neb. Code Ann. §§ 59-801, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Nebraska;

- Nev. Rev. Stat. Ann. §§ 598A.210, *et seq.*, with respect to purchases in Nevada by the plaintiff and class members, who paid substantially higher prices for inhaled beclomethasone dipropionate products in actions and transactions occurring substantially within Nevada;

- N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New Hampshire;

- N.J. State. Ann. § 56:9-3, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New Jersey;

- N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New Mexico;

- N.Y. Gen. Bus. Law § 340 with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New York;

- N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in North Carolina;

- N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in North Dakota;

- Ore. Rev. Stat. §§ 646.705, *et seq.*, and 646.725, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Oregon;

- R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Rhode Island;

- S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in South Dakota;

- Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Tennessee;

- Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to the purchases of inhaled beclomethasone dipropionate products by plaintiff and class members who reside in or are citizens of Utah;

- Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Vermont;

- W. Va. Code § 47-18-1, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in West Virginia;

- Wis. Stat. §§ 133.01, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Wisconsin, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby the plaintiff and members of the class paid substantially higher prices for inhaled beclomethasone dipropionate products purchased in Wisconsin.

651. As a direct and proximate result of Teva's unlawful maintenance of market power, the plaintiff and members of the class have been injured in their business or property by Teva's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their beclomethasone dipropionate products than they would have paid in the absence of those violations. Such injury in the form of overcharges is an injury of the type antitrust laws were designed to prevent and remedy, and flows from that which makes Teva's conduct unlawful. The plaintiff and members of the class are the proper entities to bring a case concerning this conduct.

652. The plaintiff and the class seek damages and multiple damages as permitted by law for their injuries by Teva's violations of the above statutes.

653. The plaintiff, through their counsel, has sent or will send letters to the relevant state attorneys general as required by Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); 815 Illinois Compiled Statutes § 505/10a(d); Massachusetts General Laws ch. 93A § 10; Minnesota Statutes Ann. § 325D.63; Montana Code Ann. § 30-14-133; Nevada Revised Statute § 598A.210(3); New Hampshire Revised Statutes Ann. § 358-A:10; New York General Business Law § 340(4); Oregon Revised Statutes Ann. § 646.780; Rhode Island General Laws § 6.36.21; and Utah Code § 76-10-3109.

FOURTH CLAIM FOR RELIEF
Monopolization Under State Antitrust Laws – Sham Litigation
Against all defendants

654. The plaintiff incorporates by reference and re-allege all preceding paragraphs and allegations, as though set forth fully herein.

655. A litigation is a sham if (1) the claims, positions, or arguments advanced are objectively meritless, such that no reasonable brand-name drugmaker in Teva's position could reasonably have expected to prevail and (2) the suit is subjectively motivated by an intention to harm competition by using the litigation process as a weapon. In the context of pharmaceutical Hatch-Waxman patent infringement suits, courts in this District have recognized two ways in which the first part of this test is satisfied.

656. First, a litigation may be objectively unreasonable if a reasonable brand-name drugmaker in Teva's position would have known or should have known that the asserted patents could not be adjudicated in a pre-generic launch Hatch-Waxman litigation because they were not properly listable in the Orange Book to begin with.

657. Second, a litigation may be objectively unreasonable if a reasonable brand-name drugmaker in Teva's position would not have reasonably expected to succeed in proving that its asserted patents were valid, enforceable, and infringed.

658. As alleged above, Teva's lawsuits against Cipla and Aurobindo were shams because a reasonable company in Teva's position would have or should have known—especially because of the First Circuit's *Lantus* decision mere months earlier that reaffirmed the plain language of the statutory listing requirements—that the patents it asserted against Cipla and Aurobindo should not have been listed in the Orange Book, and that, therefore, it had no standing to sue over those patents until after a generic product launched.

659. Teva ignored this because its intent, aim, and goal was to use those litigations to frustrate competition. By simply suing, it triggered automatic thirty-month delays in the approval of Cipla and Aurobindo's products. And by tactically and selectively stipulating to the dismissal of patents to ensure that, whatever the outcome of the litigation, neither Cipla nor Aurobindo could trigger the first-filer's obligation to launch generic QVAR (which would have thwarted Teva's attempts at delay).

660. Teva's sham litigations substantially harmed competition in the relevant market. There is and was no non-pretextual, procompetitive justification for Teva's actions that outweighs their harmful effects. Even if there were some conceivable justification that Teva could assert, Teva's conduct is and was broader than necessary to achieve such a purpose.

661. But for Teva's sham litigations, generic manufacturers of inhaled beclomethasone dipropionate would have been able to fairly compete with Teva in a full and timely manner, and the plaintiff and class members, who are third-party payors, would have substituted lower-priced generic inhaled beclomethasone dipropionate for some or all of their QVAR and QVAR Redihaler purchases and/or paid lower prices for their branded QVAR and QVAR Redihaler purchases.

662. Through its sham litigations, Teva intentionally and wrongfully maintained its market power with respect to QVAR and QVAR Redihaler in violation of the following state laws:

- Arizona Rev. Stat. §§ 44-1403 *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Arizona;
- Cal. Bus. & Prof. Code §§ 16700, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in California;
- Conn. Gen. Stat. Ann. §§ 35-26, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Connecticut;
- D.C. Code §§ 28-4503, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in the District of Columbia;

- Haw. Rev. Stat. § 480, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Hawaii;

- Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*, and 740 Ill. Comp. Stat. §§ 10/3, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Illinois;

- Iowa Code § 553.4, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Iowa;

- Kan. Stat. Ann. §§ 50-112, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Kansas;

- Mass. Gen. L. ch. 93A, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Massachusetts, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Maine;

- Md. Code Ann. Com. Law, §§ 11-204, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Maryland;

- Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Michigan;

- Minn. Stat. §§ 325d.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Minnesota;

- Miss. Code. Ann. §§ 75-21-3, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Mississippi;

- Mont. Code Ann. § 30-14-205, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Montana;

- Neb. Code Ann. §§ 59-801, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Nebraska;

- Nev. Rev. Stat. Ann. §§ 598A.210, *et seq.*, with respect to purchases in Nevada by the plaintiff and class members, who paid substantially higher prices for inhaled beclomethasone dipropionate products in actions and transactions occurring substantially within Nevada;

- N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New Hampshire;

- N.J. State. Ann. § 56:9-3, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New Jersey;

- N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New Mexico;

- N.Y. Gen. Bus. Law § 340 with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in New York;

- N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in North Carolina;

- N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in North Dakota;

- Ore. Rev. Stat. §§ 646.705, *et seq.*, and 646.725, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Oregon;

- R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Rhode Island;

- S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in South Dakota;

- Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Tennessee;

- Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to the purchases of inhaled beclomethasone dipropionate products by plaintiff and class members who reside in or are citizens of Utah;

- Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Vermont;

- W. Va. Code § 47-18-1, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in West Virginia;

- Wis. Stat. §§ 133.01, *et seq.*, with respect to the plaintiffs' and class members' purchases of inhaled beclomethasone dipropionate products in Wisconsin, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby the plaintiff and members of the class paid substantially higher prices for inhaled beclomethasone dipropionate products purchased in Wisconsin.

663. As a direct and proximate result of Teva's unlawful maintenance of market power, the plaintiff and members of the class have been injured in their business or property by Teva's antitrust violations. Their injury consists of having paid, and continuing to pay, higher prices for their beclomethasone dipropionate products than they would have paid in the absence of those violations. Such injury in the form of overcharges is an injury of the type antitrust laws were designed to prevent and remedy, and flows from that which makes Teva's conduct unlawful. The plaintiff and members of the class are the proper entities to bring a case concerning this conduct.

664. The plaintiff and the class seek damages and multiple damages as permitted by law for their injuries by Teva's violations of the above statutes.

665. The plaintiff, through their counsel, has sent or will send letters to the relevant state attorneys general as required by Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); 815 Illinois Compiled Statutes § 505/10a(d); Massachusetts General Laws ch. 93A § 10; Minnesota Statutes Ann. § 325D.63; Montana Code Ann. § 30-14-133; Nevada Revised Statute § 598A.210(3); New Hampshire Revised Statutes Ann. § 358-A:10; New York General Business Law § 340(4); Oregon Revised Statutes Ann. § 646.780; Rhode Island General Laws § 6.36.21; and Utah Code § 76-10-3109.

FIFTH CLAIM FOR RELIEF
Unfair Methods of Competition, and Unfair and Deceptive Acts, in Violation of State Consumer Protection Laws
Against all defendants

666. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

667. Teva has engaged in unfair competition; and/or unfair, unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Teva's anticompetitive, deceptive, unfair and/or unconscionable acts or practices, the plaintiff and members of the class were deprived of the opportunity to purchase less expensive AB-rated generic versions of QVAR and/or QVAR Redihaler, and were instead forced to pay higher prices.

668. Teva's overarching scheme, as alleged in this Complaint and in the First Claim for Relief, violates the following state consumer protection laws:

- Alaska Stat. §§ 45.50.471, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Alaska by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Alaska;

- Ark. Code Ann. §§ 4-88-107, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Arkansas by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Arkansas;

- Cal. Bus. & Prof. Code § 17200, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in California by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in California. In particular, Teva has engaged in an unlawful business practices in violation of Cal. Bus. & Prof. Code § 17200, et seq., by violating Cal. Bus. & Prof. Code § 16700, et seq., and Cal. Health and Safety Code § 134002;

- Conn. Gen. Stat. §§ 42-110a, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Connecticut by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Connecticut;

- Del. Code. Ann., tit. 6 § 2511, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Delaware by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Delaware;

- D.C. Code §§ 28-3901, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in District of Columbia by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in District of Columbia;

- Fla. Stat. § 501.201, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Florida by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Florida;

- Haw. Rev. Stat. §§ 480 *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Hawaii by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Hawaii;

- 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Illinois by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Illinois;

- Ind. Code Ann. § 24-5-0.5-1, *et seq.*, with respect to purchases of QVAR and QVAR Redihaler in Indiana or by class members residing in Indiana, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Iowa Code §§ 714.16, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Iowa by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Iowa;

- 5 Me. Rev. Stat. § 207, *et seq.*, with respect to purchases of QVAR or QVAR Redihaler in Maine or by class members residing in Maine, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Mass. Gen. L. ch. 93A, with respect to purchases of QVAR or QVAR Redihaler in Massachusetts or by class members residing in Massachusetts, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Md. Code Ann., Com. Law §§ 13-101, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Maryland by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Maryland;

- Minn. Stat. §§ 8.31, 325F.67, 325F.68, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Minnesota by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Minnesota;

- Miss. Code. § 75-24-1, *et seq.*, with respect to purchases of QVAR or QVAR Redihaler in Mississippi or by class members

residing in Mississippi, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Nebraska by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Nebraska;

- Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Nevada by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Nevada;

- N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New Hampshire by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New Hampshire;

- N.J. Stat. Ann. §§ 56:8-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New Jersey by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New Jersey;

- N.M. Stat. § 57-12-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New Mexico by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New Mexico;

- N.Y. Gen. Bus. Law § 349, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New York by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New York.[25]

- N.C. Gen. Stat. § 75-1.1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in North Carolina by class members and/or purchases of inhaled

[25] To the extent New York law so requires, the plaintiff hereby forgoes any minimum or punitive damages in order to preserve the right of New York class members to recover actual damages by way of a class action.

beclomethasone dipropionate products by class members residing in North Carolina;

- N.D. Cent. Code. §§51-15-01, *et seq*. with respect to purchases of inhaled beclomethasone dipropionate products in North Dakota by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in North Dakota;

- Ohio Rev. Code Ann. §§ 1345.01, *et seq*., with respect to purchases of inhaled beclomethasone dipropionate products in Ohio by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Ohio;

- Okla. Stat. tit. 15, §§ 751, *et seq*., with respect to purchases of inhaled beclomethasone dipropionate products in Oklahoma by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Oklahoma;

- S.D. Codified Laws §§ 37-24-1, *et seq*., with respect to purchases of inhaled beclomethasone dipropionate products in South Dakota by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in South Dakota;

- Tex. Bus. & Prof. Code § 17.41, *et seq*., with respect to purchases of QVAR or QVAR Redihaler in Texas or by class members residing in Texas, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Utah Code Ann. §§ 13-11-1, *et seq*., with respect to purchases of inhaled beclomethasone dipropionate products in Utah by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Utah;

- Vt. Stat. Ann. 9, §§ 2453, *et seq*., with respect to purchases of inhaled beclomethasone dipropionate products in Vermont by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Vermont;

- Va. Stat. Ann. §§ 59.1-196, *et seq*., with respect to purchases of inhaled beclomethasone dipropionate products in Virginia by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Virginia;

- Wash. Rev. Code §§ 1986.010, *et seq*., with respect to purchases of inhaled beclomethasone dipropionate products in Washington by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Washington; and

- Wyo. Stat. Ann. § 40-12-101, *et seq*., with respect to purchases of QVAR and QVAR Redihaler in Wyoming or by class members residing in Wyoming, the statutorily required notice having been mailed to the defendants on May 23, 2023.

669. The plaintiff and members of the class have been injured in their business and property by reason of Teva's anticompetitive, unfair, unconscionable, and/or deceptive acts or practices alleged in this Court. Their injury consists of paying higher prices for inhaled beclomethasone dipropionate products than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Teva's unlawful conduct.

SIXTH CLAIM FOR RELIEF
Violations of State Consumer Protection Laws – Wrongful QVAR Orange Book Listings
Against all defendants

670. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

671. Teva has engaged in unfair competition; and/or unfair, unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Teva's anticompetitive, deceptive, unfair and/or unconscionable acts or practices, the plaintiff and members of the class were deprived of the opportunity to purchase less expensive AB-rated

generic versions of QVAR and/or QVAR Redihaler, and were instead forced to pay higher prices.

672. Teva's conduct as alleged in this Complaint and in the Second Claim for Relief violates the following state consumer protection laws:

- Alaska Stat. §§ 45.50.471, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Alaska by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Alaska;
- Ark. Code Ann. §§ 4-88-107, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Arkansas by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Arkansas;
- Cal. Bus. & Prof. Code § 17200, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in California by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in California. In particular, Teva has engaged in an unlawful business practices in violation of Cal. Bus. & Prof. Code § 17200, et seq., by violating Cal. Bus. & Prof. Code § 16700, et seq., and Cal. Health and Safety Code § 134002;
- Conn. Gen. Stat. §§ 42-110a, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Connecticut by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Connecticut;
- Del. Code. Ann., tit. 6 § 2511, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Delaware by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Delaware;
- D.C. Code §§ 28-3901, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in District of Columbia by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in District of Columbia;

- Fla. Stat. § 501.201, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Florida by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Florida;

- Haw. Rev. Stat. §§ 480 *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Hawaii by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Hawaii;

- 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Illinois by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Illinois;

- Ind. Code Ann. § 24-5-0.5-1, *et seq.*, with respect to purchases of QVAR and QVAR Redihaler in Indiana or by class members residing in Indiana, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Iowa Code §§ 714.16, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Iowa by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Iowa;

- 5 Me. Rev. Stat. § 207, *et seq.*, with respect to purchases of QVAR or QVAR Redihaler in Maine or by class members residing in Maine, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Mass. Gen. L. ch. 93A, with respect to purchases of QVAR or QVAR Redihaler in Massachusetts or by class members residing in Massachusetts, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Md. Code Ann., Com. Law §§ 13-101, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Maryland by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Maryland;

- Minn. Stat. §§ 8.31, 325F.67, 325F.68, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Minnesota by class members and/or purchases of inhaled

beclomethasone dipropionate products by class members residing in Minnesota;

- Miss. Code. § 75-24-1, *et seq.*, with respect to purchases of QVAR or QVAR Redihaler in Mississippi or by class members residing in Mississippi, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Nebraska by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Nebraska;

- Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Nevada by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Nevada;

- N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New Hampshire by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New Hampshire;

- N.J. Stat. Ann. §§ 56:8-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New Jersey by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New Jersey;

- N.M. Stat. § 57-12-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New Mexico by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New Mexico;

- N.Y. Gen. Bus. Law § 349, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New York by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New York.[26]

[26] To the extent New York law so requires, the plaintiff hereby forgoes any minimum or punitive damages in order to preserve the right of New York class members to recover actual damages by way of a class action.

- N.C. Gen. Stat. § 75-1.1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in North Carolina by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in North Carolina;

- N.D. Cent. Code. §§51-15-01, *et seq.* with respect to purchases of inhaled beclomethasone dipropionate products in North Dakota by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in North Dakota;

- Ohio Rev. Code Ann. §§ 1345.01, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Ohio by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Ohio;

- Okla. Stat. tit. 15, §§ 751, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Oklahoma by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Oklahoma;

- S.D. Codified Laws §§ 37-24-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in South Dakota by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in South Dakota;

- Tex. Bus. & Prof. Code § 17.41, *et seq.*, with respect to purchases of QVAR or QVAR Redihaler in Texas or by class members residing in Texas, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Utah Code Ann. §§ 13-11-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Utah by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Utah;

- Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Vermont by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Vermont;

- Va. Stat. Ann. §§ 59.1-196, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Virginia by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Virginia;

- Wash. Rev. Code §§ 1986.010, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Washington by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Washington; and

- Wyo. Stat. Ann. § 40-12-101, *et seq.*, with respect to purchases of QVAR and QVAR Redihaler in Wyoming or by class members residing in Wyoming, the statutorily required notice having been mailed to the defendants on May 23, 2023.

673. The plaintiff and members of the class have been injured in their business and property by reason of Teva's anticompetitive, unfair, unconscionable, and/or deceptive acts or practices alleged. Their injury consists of paying higher prices for inhaled beclomethasone dipropionate products than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Teva's unlawful conduct.

SEVENTH CLAIM FOR RELIEF
Violations of State Consumer Protection Laws – Unlawful Reverse Payment
Against all defendants

674. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

675. Teva has engaged in unfair competition; and/or unfair, unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Teva's anticompetitive,

deceptive, unfair and/or unconscionable acts or practices, the plaintiff and members of the class were deprived of the opportunity to purchase less expensive AB-rated generic versions of QVAR and/or QVAR Redihaler, and were instead forced to pay higher prices.

676. Teva's conduct as alleged in this complaint and in the Third Claim for Relief violates the following state consumer protection laws:

- Alaska Stat. §§ 45.50.471, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Alaska by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Alaska;
- Ark. Code Ann. §§ 4-88-107, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Arkansas by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Arkansas;
- Cal. Bus. & Prof. Code § 17200, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in California by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in California. In particular, Teva has engaged in unlawful business practices in violation of Cal. Bus. & Prof. Code § 17200, et seq., by violating Cal. Bus. & Prof. Code § 16700, et seq., and Cal. Health and Safety Code § 134002;
- Conn. Gen. Stat. §§ 42-110a, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Connecticut by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Connecticut;
- Del. Code. Ann., tit. 6 § 2511, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Delaware by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Delaware;
- D.C. Code §§ 28-3901, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in District of Columbia by class members and/or purchases of inhaled

beclomethasone dipropionate products by class members residing in District of Columbia;

- Fla. Stat. § 501.201, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Florida by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Florida;

- Haw. Rev. Stat. §§ 480 *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Hawaii by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Hawaii;

- 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Illinois by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Illinois;

- Ind. Code Ann. § 24-5-0.5-1, *et seq.*, with respect to purchases of QVAR and QVAR Redihaler in Indiana or by class members residing in Indiana, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Iowa Code §§ 714.16, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Iowa by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Iowa;

- 5 Me. Rev. Stat. § 207, *et seq.*, with respect to purchases of QVAR or QVAR Redihaler in Maine or by class members residing in Maine, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Mass. Gen. L. ch. 93A, with respect to purchases of QVAR or QVAR Redihaler in Massachusetts or by class members residing in Massachusetts, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Md. Code Ann., Com. Law §§ 13-101, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Maryland by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Maryland;

- Minn. Stat. §§ 8.31, 325F.67, 325F.68, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Minnesota by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Minnesota;

- Miss. Code. § 75-24-1, *et seq.*, with respect to purchases of QVAR or QVAR Redihaler in Mississippi or by class members residing in Mississippi, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Nebraska by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Nebraska;

- Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Nevada by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Nevada;

- N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New Hampshire by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New Hampshire;

- N.J. Stat. Ann. §§ 56:8-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New Jersey by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New Jersey;

- N.M. Stat. § 57-12-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New Mexico by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New Mexico;

- N.Y. Gen. Bus. Law § 349, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New York by class members and/or purchases of inhaled beclomethasone

dipropionate products by class members residing in New York.[27]

- N.C. Gen. Stat. § 75-1.1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in North Carolina by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in North Carolina;

- N.D. Cent. Code. §§51-15-01, *et seq.* with respect to purchases of inhaled beclomethasone dipropionate products in North Dakota by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in North Dakota;

- Ohio Rev. Code Ann. §§ 1345.01, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Ohio by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Ohio;

- Okla. Stat. tit. 15, §§ 751, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Oklahoma by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Oklahoma;

- S.D. Codified Laws §§ 37-24-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in South Dakota by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in South Dakota;

- Tex. Bus. & Prof. Code § 17.41, *et seq.*, with respect to purchases of QVAR or QVAR Redihaler in Texas or by class members residing in Texas, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Utah Code Ann. §§ 13-11-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Utah by

[27] To the extent New York law so requires, the plaintiff hereby forgoes any minimum or punitive damages in order to preserve the right of New York class members to recover actual damages by way of a class action.

class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Utah;

- Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Vermont by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Vermont;

- Va. Stat. Ann. §§ 59.1-196, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Virginia by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Virginia;

- Wash. Rev. Code §§ 1986.010, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Washington by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Washington; and

- Wyo. Stat. Ann. § 40-12-101, *et seq.*, with respect to purchases of QVAR and QVAR Redihaler in Wyoming or by class members residing in Wyoming, the statutorily required notice having been mailed to the defendants on May 23, 2023.

677. The plaintiff and members of the class have been injured in their business and property by reason of Teva's anticompetitive, unfair, unconscionable, and/or deceptive acts or practices alleged in this Court. Their injury consists of paying higher prices for inhaled beclomethasone dipropionate products than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Teva's unlawful conduct.

EIGHTH CLAIM FOR RELIEF
Violations of State Consumer Protection Laws – Sham Litigation
Against all defendants

678. The plaintiff incorporates by reference and re-allege all preceding paragraphs and allegations, as though set forth fully herein.

679. Teva has engaged in unfair competition; and/or unfair, unconscionable, and/or deceptive acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Teva's anticompetitive, deceptive, unfair and/or unconscionable acts or practices, the plaintiff and members of the class were deprived of the opportunity to purchase less expensive AB-rated generic versions of QVAR and/or QVAR Redihaler, and were instead forced to pay higher prices.

680. Teva's conduct as alleged in this Complaint and in the Fourth Claim for Relief violates the following state consumer protection laws:

- Alaska Stat. §§ 45.50.471, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Alaska by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Alaska;
- Ark. Code Ann. §§ 4-88-107, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Arkansas by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Arkansas;
- Cal. Bus. & Prof. Code § 17200, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in California by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in California. In particular, Teva has engaged in unlawful business practices in violation of Cal. Bus. & Prof. Code § 17200, et seq., by violating Cal. Bus. & Prof. Code § 16700, et seq., and Cal. Health and Safety Code § 134002;
- Conn. Gen. Stat. §§ 42-110a, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Connecticut by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Connecticut;
- Del. Code. Ann., tit. 6 § 2511, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Delaware

by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Delaware;

- D.C. Code §§ 28-3901, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in District of Columbia by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in District of Columbia;

- Fla. Stat. § 501.201, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Florida by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Florida;

- Haw. Rev. Stat. §§ 480 *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Hawaii by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Hawaii;

- 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Illinois by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Illinois;

- Ind. Code Ann. § 24-5-0.5-1, *et seq.*, with respect to purchases of QVAR and QVAR Redihaler in Indiana or by class members residing in Indiana, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Iowa Code §§ 714.16, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Iowa by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Iowa;

- 5 Me. Rev. Stat. § 207, *et seq.*, with respect to purchases of QVAR or QVAR Redihaler in Maine or by class members residing in Maine, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Mass. Gen. L. ch. 93A, with respect to purchases of QVAR or QVAR Redihaler in Massachusetts or by class members residing in Massachusetts, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Md. Code Ann., Com. Law §§ 13-101, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Maryland by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Maryland;

- Minn. Stat. §§ 8.31, 325F.67, 325F.68, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Minnesota by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Minnesota;

- Miss. Code. § 75-24-1, *et seq.*, with respect to purchases of QVAR or QVAR Redihaler in Mississippi or by class members residing in Mississippi, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Nebraska by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Nebraska;

- Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Nevada by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Nevada;

- N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New Hampshire by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New Hampshire;

- N.J. Stat. Ann. §§ 56:8-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New Jersey by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New Jersey;

- N.M. Stat. § 57-12-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New Mexico by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New Mexico;

- N.Y. Gen. Bus. Law § 349, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in New York by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in New York.[28]

- N.C. Gen. Stat. § 75-1.1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in North Carolina by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in North Carolina;

- N.D. Cent. Code. §§51-15-01, *et seq.* with respect to purchases of inhaled beclomethasone dipropionate products in North Dakota by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in North Dakota;

- Ohio Rev. Code Ann. §§ 1345.01, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Ohio by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Ohio;

- Okla. Stat. tit. 15, §§ 751, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Oklahoma by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Oklahoma;

- S.D. Codified Laws §§ 37-24-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in South Dakota by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in South Dakota;

- Utah Code Ann. §§ 13-11-1, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Utah by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Utah;

[28] To the extent New York law so requires, the plaintiff hereby forgoes any minimum or punitive damages in order to preserve the right of New York class members to recover actual damages by way of a class action.

- Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Vermont by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Vermont;

- Tex. Bus. & Prof. Code § 17.41, *et seq.*, with respect to purchases of QVAR or QVAR Redihaler in Texas or by class members residing in Texas, the statutorily required notice having been mailed to the defendants on May 23, 2023;

- Va. Stat. Ann. §§ 59.1-196, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Virginia by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Virginia;

- Wash. Rev. Code §§ 1986.010, *et seq.*, with respect to purchases of inhaled beclomethasone dipropionate products in Washington by class members and/or purchases of inhaled beclomethasone dipropionate products by class members residing in Washington; and

- Wyo. Stat. Ann. § 40-12-101, *et seq.*, with respect to purchases of QVAR and QVAR Redihaler in Wyoming or by class members residing in Wyoming, the statutorily required notice having been mailed to the defendants on May 23, 2023.

681. The plaintiff and members of the class have been injured in their business and property by reason of Teva's anticompetitive, unfair, unconscionable, and/or deceptive acts or practices alleged in this Court. Their injury consists of paying higher prices for inhaled beclomethasone dipropionate products than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Teva's unlawful conduct.

NINTH CLAIM FOR RELIEF
Unjust Enrichment Under State Law
Against all defendants

682. The plaintiff incorporates by reference and re-alleges all preceding paragraphs and allegations, as though set forth fully herein.

683. To the extent required, this claim is pleaded in the alternative to the other claims in this complaint.

684. Teva has financially benefitted from overcharges on sales of inhaled beclomethasone dipropionate products, which resulted from the unlawful and inequitable conduct alleged in this complaint. The plaintiff and members of the class have borne these overcharges when they purchased and/or reimbursed all or part of the purchase price of inhaled beclomethasone dipropionate products.

685. The benefits conferred on the defendants are substantial and measurable: the extent to which the defendants have been unjustly enriched by their overarching anticompetitive scheme may be ascertained by review of both sales records and their unlawful agreement with Amneal.

686. There is a gross disparity between the price that the plaintiff and class members paid for QVAR and QVAR Redihaler and what they would have paid for less expensive generic versions of the drug product, which should and would have been available as early as 2015, and no later than 2021, but for Teva's unlawful and inequitable conduct.

687. Teva repeatedly and continuously received financial benefits at the expense of the plaintiff and the class each time a plaintiff or a class member paid for

all or part of a prescription of QVAR or QVAR Redihaler on or after the date on which generic inhaled beclomethasone dipropionate products should have become available.

688. It would be futile for the plaintiff and members of the class to seek a remedy from any party with whom they had or have privity of contract. The defendants have paid no consideration to any other person for any of the benefits they received indirectly from the plaintiff and members of the class.

689. It would be futile for the plaintiff and members of the class to seek to exhaust any remedy against an intermediary in the chain of distribution from which they purchased inhaled beclomethasone dipropionate products, as those intermediaries cannot reasonably be expected to compensate the plaintiff and members of the class for Teva's unlawful conduct.

690. The financial benefits that Teva derived rightfully belong to the plaintiff and members of the class, who paid anticompetitive prices that inured to Teva's benefit.

691. It would be inequitable under the unjust enrichment principles of the states listed below for Teva to retain any of the overcharges that the plaintiff and members of the class paid for inhaled beclomethasone dipropionate products, which were derived from Teva's anticompetitive, unfair, unconscionable, and/or deceptive methods, acts, or trade practices.

692. Teva should be compelled to disgorge all unlawful or inequitable proceeds received by them into a common fund for the benefit of the plaintiff and members of the class.

693. A constructive trust should be imposed upon all unlawful or inequitable sums that Teva received, which arise from overpayments for QVAR and QVAR Redihaler by the plaintiff and members of the class.

694. The plaintiff and members of the class have no adequate remedy at law.

695. By engaging in the foregoing unlawful or inequitable conduct, which deprived the plaintiff and members of the class of the opportunity to purchase lower-priced generic versions of beclomethasone dipropionate products and forced them to pay higher prices for QVAR and QVAR Redihaler, Teva has been unjustly enriched in violation of the common law of all fifty states and commonwealths.

696. By virtue of the foregoing, the plaintiff and members of the class are entitled to recover the amount of Teva's unjust enrichment, to be determined at trial, and other relief permitted by law.

TENTH CLAIM FOR RELIEF
Injunctive Relief Under Section 2 of the Sherman Act
(15 U.S.C. § 2)
Against all defendants

697. The plaintiff incorporates by reference the preceding allegations.

698. Based on the conduct alleged in this complaint, the defendants have engaged in conduct that violates Section 2 of the Sherman Act.

699. That conduct involves unlawfully delaying generic competition to Teva's QVAR franchise.

700. Unless enjoined, Teva will continue to thwart competition in the market for beclomethasone dipropionate, including by submitting information for, and maintaining, improper Orange Book listings; leveraging unlawfully listed patents

against would-be competitors; and executing a second product hop from QVAR Redihaler to QVAR Digihaler.

701. The plaintiff requests that the Court grant injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, as may be necessary and appropriate to prevent Teva from further destroying competition and to restore competition in the market for inhaled beclomethasone dipropionate products.

XII. JURY DEMAND

702. The plaintiff, on behalf of itself and the class, demands a jury trial on all issues triable of right before a jury.

XIII. PRAYER FOR RELIEF

The plaintiff requests that the Court enter judgment in their favor and grant the following relief:

703. Treble or at least double damages under the applicable state laws;

704. Compensatory and punitive damages;

705. Appropriate equitable and injunctive relief;

706. Court costs and reasonable attorneys' fees;

707. Prejudgment and post-judgment interest; and

708. Any further relief the Court deems proper and just.

Dated: September 1, 2023

Respectfully submitted,

/s/ Steven L. Groopman

BERMAN TABACCO

Kathleen M. Donovan-Maher (BBO #558947)
Leslie R. Stern (BBO #631201)

Steven L. Groopman (BBO #568933)
Kristie A. LaSalle (BBO #692891)
Christina L. Gregg (BBO #709220)
One Liberty Square
Boston, Massachusetts 02109
Telephone: (617) 542-8300
Facsimile: (617) 542-1194
kdonovanmaher@bermantabacco.com
lstern@bermantabacco.com
sgroopman@bermantabacco.com
klasalle@bermantabacco.com
cgregg@bermantabacco.com

Joseph J. Tabacco, Jr. (BBO #491260)
Nicole Lavallee (*pro hac* forth coming)
Todd A. Seaver (BBO #645874)
Matthew D. Pearson (*pro hac* forthcoming)
425 California St, Suite 2300
San Francisco, CA 94104
Telephone: (415) 433-3200
Facsimile: (415) 433-6382
jtabacco@bermantabacco.com
nlavallee@bermantabacco.com
tseaver@bermandetabacco.com
mpearson@bermantabacco.com

Joseph M. Vanek (BBO # 551083)
Eamon Kelly (*pro hac* forthcoming)
Martin V. Sinclair, Jr. (*pro hac* forthcoming)
David Lesht (*pro hac* forthcoming)
SPERLING & SLATER, LLC
55 W. Monroe Street
Suite 3200
Chicago, IL 60603
Tel: (312) 641-3200
jvanek@sperling-law.com
ekelly@sperling-law.com
msinclair@sperling-law.com
dlesht@sperling-law.com

Steve D. Shadowen (*pro hac* forthcoming)
Richard M. Brunell (*pro hac* forthcoming)
Matthew C. Weiner (*pro hac* forthcoming)
Tina J. Miranda (*pro hac* forthcoming)

HILLIARD & SHADOWEN LLP
1135 W. 6th Street, Suite 125
Austin, TX 78703
Tel: (855) 344-3298
steve@hilliardshadowenlaw.com
rbrunell@hilliardshadowenlaw.com
matt@hilliardshadowenlaw.com
tmiranda@hilliardshadowenlaw.com

Counsel for the Plaintiffs and the Proposed Class

Brian P. Murray (*pro hac* forthcoming)
Lee Albert (*pro hac* forthcoming)
Brian D. Brooks (*pro hac* forthcoming)
GLANCY PRONGAY & MURRAY LLP
230 Park Avenue, Suite 358
New York, NY 10169
Telephone: (212) 682-5340
bmurray@glancylaw.com
lalbert@glancylaw.com
bbrooks@glancylaw.com

Counsel for Jacksonville Trust

Christopher M. Burke (*pro hac* forthcoming)
Walter Noss (*pro hac* forthcoming)
Yifan (Kate) Lv(*pro hac* forthcoming)
KOREIN TILLERY P.C.
707 Broadway, Suite 1410
San Diego, CA 92101
Telephone: (619) 6225-5620
cburke@koreintillery.com
wnoss@koreintillery.com
klv@koreintillery.com

Allan Steyer (*pro hac* forthcoming)
STEYER LOWENTHAL BOODROKAS ALVAREZ & SMITH LLP
235 Pine Street, 15th Floor
San Francisco, CA 94104
Telephone: (415) 421-3400
asteyer@steyerlaw.com

Arthur Bailey (*pro hac* forthcoming)
RUPP PFALGRAF LLC
111 West 2nd Street, #1100
Jamestown, NY 14701
Telephone: (716) 664-2967
bailey@rupppfalz.com

Counsel for New York State Teamsters Council Health & Hospital Fund

APPENDIX A: Orange Book Listings for QVAR Redihaler

Patent No.	Title	Issue Date	Listing Date	Expiry	Claims beclomethasone dipropionate drug product?
6,446,627	*Inhaler Dose Counter*	9/10/2002	8/2017	12/18/2017	No
7,637,260	*Medicament dispensing device with a multimaterial diaphragm bounding a pneumatic force chamber*	12/29/2009	8/2017	11/2/2022	No
8,132,712	*Metered-dose inhaler*	3/13/2012	8/2017	9/7/2028	No
8,931,476	*Inhaler*	1/13/2015	8/2017	7/17/2031	No[29]
10,022,509	*Dose counter for inhaler having a bore and shaft arrangement*	7/17/2018	7/2018	5/18/2031	No
10,022,510	*Dose counters for inhalers, inhalers and methods of assembly thereof*	7/17/2018	7/2018	5/18/2031	No
10,086,156	*Dose counter for inhaler and method for counting doses*	10/2/2018	10/2018	5/18/2031	No
10,695,512	*Dose counter for inhaler having an anti-reverse rotation actuator*	6/30/2020	7/2020	3/15/2032	No
10,792,447	*Breath actuated inhaler*	10/6/2020	10/2020	1/25/2039	Yes
11,395,888	*Inhalers and related methods*	7/26/2022	8/2022	1/26/2038	Yes
11,395,889	*Dose counter for inhaler having an anti-reverse rotation actuator*	7/26/2022	8/2022	5/18/2031	No
11,559,637	*Inhalers and related methods*	1/24/2023	2/2023	7/21/2039	No[30]
11,583,643	*Inhalers and related methods*	2/21/2023	3/2023	8/19/2041	No[36]

[29] Dependent claim 15 of the '476 patent reads "An inhaler according to claim 1, wherein the medicament is selected from the group consisting . . . *beclomethasone*" and other molecules. Beclomethasone is not the same as beclomethasone dipropionate.

[30] The '637 and '643 patents include only method-of-use claims, some of which include, as an element a method of using an inhaler containing beclomethasone dipropionate.

APPENDIX B: Orange Book Listings for QVAR

Patent No.	Title	Issue Date	Listing Date	Expiry	Claims a beclomethasone dipropionate drug product?
5,605,674	*Medicinal aerosol formulations*	2/25/1997	10/2000	2/25/2014	No
5,683,677	*Medicinal aerosol formulations*	11/4/1997	10/2000	11/4/2014	No
5,695,743	*Medicinal aerosol formulations*	12/9/1997	10/2000	7/6/2010	Yes
5,766,573	*Medicinal aerosol formulations*	6/16/1998	10/2000	11/28/2009	Yes
5,776,432	*Beclomethasone solution aerosol formulations*	7/7/1998	10/2000	7/7/2015	Yes
6,446,627	*Inhaler dose counter*	9/10/2002	6/2014	12/18/2017	No
9,463,289	*Dose counters for inhalers, inhalers and methods of assembly thereof*	10/11/2016	11/2016	5/18/2031	No
9,808,587	*Dose counter for inhaler having an anti-reverse rotation actuator*	11/7/2017	11/2017	5/18/2031	No
10,022,509	*Dose counter for inhaler having a bore and shaft arrangement*[31]	7/17/2018	7/2018	5/18/2031	No
10,022,510	*Dose counters for inhalers, inhalers and methods of assembly thereof*	7/17/2018	7/2018	5/18/2031	No
10,086,156	*Dose counter for inhaler and method for counting doses*	10/2/2018	10/2018	5/18/2031	No
10,561,808	*Dose counter for inhaler having an anti-reverse rotation actuator*	2/18/2020	3/2020	12/22/2031	No
10,695,512	*Dose counter for inhaler having an anti-reverse rotation actuator*	6/30/2020	7/2020	3/15/2032	No
11,395,889	*Dose counter for inhaler having an anti-reverse rotation actuator*	7/26/2022	8/2022	5/18/2031	No

[31] Teva listed the patents in blue font after it announced it was discontinuing its QVAR product.

CERTIFICATE OF SERVICE

I, Steven L. Groopman, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on September 1, 2023.

Dated: September 1, 2023

/s/ Steven L. Groopman
Steven L. Groopman